IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

DePuy Mitek, Inc. **a Massachusetts Corporation** **Plaintiff.** **v.** **Arthrex, Inc.** **a Delaware Corporation, and** **Pearsalls Ltd.** **a Private Limited Company** **of the United Kingdom** **Defendants.**	)))))))))))))))	**Civil No. 04-12457 PBS**

Plaintiff DePuy Mitek's Memorandum In Opposition to
Defendants' Motion *In Limine* to Preclude DePuy Mitek
From Arguing at Trial That Coating's Effect on FiberWire is Minimal
Compared to the Effect of Combining Two Different Materials

I. Introduction

Arthrex's motion is predicated on the simple, but irrelevant, fact that Mitek made an argument in its summary judgment briefing that does not repeat the wording used in its expert's report in *haec verba*. But Mitek's arguments need not parrot Dr. Brookstein's report word-for-word.

Mitek's arguments are consistent with Dr. Brookstein's opinions, as set forth in detail in his expert reports. Dr. Brookstein reported that FiberWire suture was engineered, consistent with the teaching in the Hunter 446 Patent, to achieve, through mechanical blending, the outstanding properties of two dissimilar, fiber-forming materials. He opined that the standard surface coating on FiberWire, which may further enhance the properties of the suture, does not materially affect the basic and novel properties of the invention. Arthrex's motion should be denied.

II. Mitek's Arguments are Consistent with Dr. Brookstein's Opinions

The Hunter 446 Patent claims a surgical suture formed from a braid of two dissimilar yarns. The patent explains that the direct intertwining braid of dissimilar materials provides "outstanding properties attributable to the specific properties of the dissimilar fiber-forming materials which make up the braided yarns" (Ex. 1 at 2:50-52). The Court's definition of the "basic and novel characteristics" of the invention of the Hunter 446 Patent recognizes the contribution of the *constituent elements* of the suture to its properties. The Court construed the basic and novel properties as:

> (1) a surgical suture, (2) composed of two dissimilar yarns from the lists in Claim One, (3) where at least one yarn from the first set is in direct intertwining contact with the yarn from the second set, (4) so as to improve pliability and handleability without significantly sacrificing the physical properties of the *constituent elements* of the suture.

(Ex. 2 at 18-19, emphasis added).

Dr. Brookstein explains in his report that FiberWire suture was designed to take advantage of the physical properties of the constituent elements, UHMWPE and PET, to yield a suture with improved pliability and handleability:

> · Arthrex had tried a braided suture of UHMWPE only, but its knot security was poor because the material is too slippery (Ex. 3 at ¶25).
>
> · Arthrex had tried a braided suture of PET only but its knot strength was too low (*id*.).
>
> · Arthrex engineered a braid of UHMWPE and PET to maximize the benefits of the dissimilar yarns (*id*.).
>
> · The UHMWPE/PET braid (FiberWire) had improved knot strength properties and did not slip like the UHMWPE braid (*id*.).

Dr. Brookstein also explains that the coating on FiberWire does not affect FiberWire's characteristic of having two dissimilar yarns braided together to achieve handleability and pliability without significantly sacrificing physical properties (*id*. at ¶¶24-26). The coating, he

notes, is merely a surface "lubricant" and does not prevent each yarn from contributing to the overall properties of the suture (*id*. at ¶24; Ex. 4 at ¶36). Although the coating may enhance certain suture properties, the suture still reaps the benefits of the dissimilar yarn braid in terms of handleability/pliability and physical properties (Ex. 3 at ¶¶25, 26). The coating does not cause the braided suture to lose its characteristics that are attributable to the dissimilar yarns being braided together (*id*. at ¶27).

In support of his opinion that the coating does not affect the contribution of the physical properties of the constituent elements to FiberWire suture's properties, Dr. Brookstein notes the following evidence:

· The coating on FiberWire is merely a surface "lubricant." (id. at ¶24).

· The Hunter 446 Patent explains that the direct intertwining braid of dissimilar materials provides outstanding properties and expressly contemplates that the properties of the braid can be *further improved* with a surface coating (*id*. at ¶¶32-36). The Patent teaches that the coating preferably does not cause the fibers or yarns to adhere to one another, increasing stiffness (*id*. at ¶¶33-34).

· FiberWire has a very small amount of coating. It is not applied in a thick layer or so as to melt together with the yarns to form a non-braided structure (id. at ¶27).

· Photomicrographs of FiberWire suture evidence that the coating does not permeate the braided structure and does not reside between the braid yarns (Ex. 4 at ¶39). The fibers in the FiberWire suture are not bonded together (Ex. 3 at ¶34). The photomicrographs also show that the fibers in FiberWire retain their morphological attributes so that they can contribute to the handleability, pliability, and physical properties of the suture (*id*. at ¶28). As Dr. Brookstein explained further at his deposition, a coating that permeated the braid could affect the way the yarns in the braid interact with one another and, thus, affect the structure and properties of the braid (Ex. 5 at 219:4-13; 222:7-15).

Thus, Mitek's argument that the benefit of FiberWire's coating is minimal compared to the benefits achieved by the braided materials is supported by Dr. Brookstein's opinions. FiberWire was engineered to maximize the benefits of the constituent elements of the suture, the dissimilar UHMWPE and PET yarns. Its standard surface coating, which may further enhance

certain handling properties, consistent with the express teaching in the Hunter 446 Patent, does not affect the ability of the constituent elements of the suture to contribute their dissimilar physical properties. The coating does not materially affect the basic and novel characteristics of the invention, as they are construed by the Court.

III. Conclusion

For the foregoing reasons, Mitek respectfully requests that Arthrex's motion be denied.

Dated: July 23, 2007

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CERTIFICATE OF SERVICE

I certify that I am counsel for DePuy Mitek, Inc. and that true and correct copies of:

Plaintiff DePuy Mitek's Memorandum In Opposition to Defendants' Motion *In Limine* to Preclude DePuy Mitek From Arguing at Trial That Coating's Effect on FiberWire is Minimal Compared to the Effect of Combining Two Different Materials

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EXHIBIT 1

US005314446A

United States Patent [19]

Hunter et al.

[11] Patent Number: 5,314,446

[45] Date of Patent: May 24, 1994

[54] STERILIZED HETEROGENEOUS BRAIDS

[75] Inventors: Alastair W. Hunter, Bridgewater; Arthur Taylor, Jr., Plainfield, both of N.J.; Mark Steckel, Maineville, Ohio

[73] Assignee: Ethicon, Inc., Somerville, N.J.

[21] Appl. No.: 838,511

[22] Filed: Feb. 19, 1992

[51] Int. Cl.[5] D04C 1/00

[52] U.S. Cl. 606/231; 606/228; 87/7; 87/9; 428/370

[58] Field of Search 606/228, 230, 231; 87/7, 8, 9; 428/225

[56] References Cited

U.S. PATENT DOCUMENTS

3,187,752	6/1965	Glick	128/335.5
3,463,158	8/1969	Schmitt et al.	606/228
3,527,650	9/1970	Block	117/7
3,636,956	1/1972	Schneider	128/335.5
3,942,532	3/1976	Hunter et al.	128/335.5
4,043,344	8/1977	Landi et al.	128/335.5
4,047,533	8/1977	Perciaccante et al.	128/335.5
4,052,988	10/1977	Doddi et al.	128/335.5
4,141,087	2/1979	Shalaby et al.	3/1
4,470,941	9/1984	Kurtz	264/136
4,624,256	11/1986	Messier et al.	128/335.5
4,946,467	8/1990	Ohi et al.	606/228
4,959,069	9/1990	Brennan et al.	606/228
4,979,956	12/1990	Silverstrini	623/13
5,116,360	5/1992	Pinchuk et al.	623/1
5,147,400	9/1992	Kaplan et al.	623/13

FOREIGN PATENT DOCUMENTS

2949920	3/1981	Fed. Rep. of Germany	A61F 1/00
WO86/00020	1/1986	PCT Int'l Appl.	A61L 17/00
2082213	8/1980	United Kingdom	.
2218312A	11/1989	United Kingdom	A01K 91/00

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[57] ABSTRACT

Heterogeneous braided multifilament of first and second set of yarns mechanically blended by braiding, in which first and second set of yarns are composed of different fiber-forming materials.

Heterogeneous braids are useful for preparation of surgical sutures and ligatures.

12 Claims, 3 Drawing Sheets

FIG-1

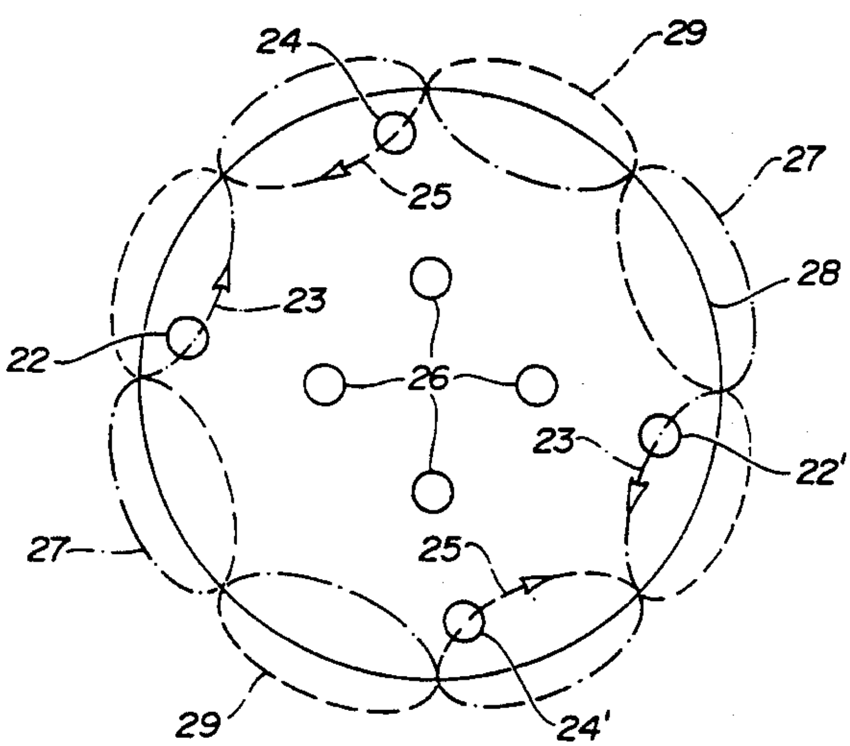


FIG-2

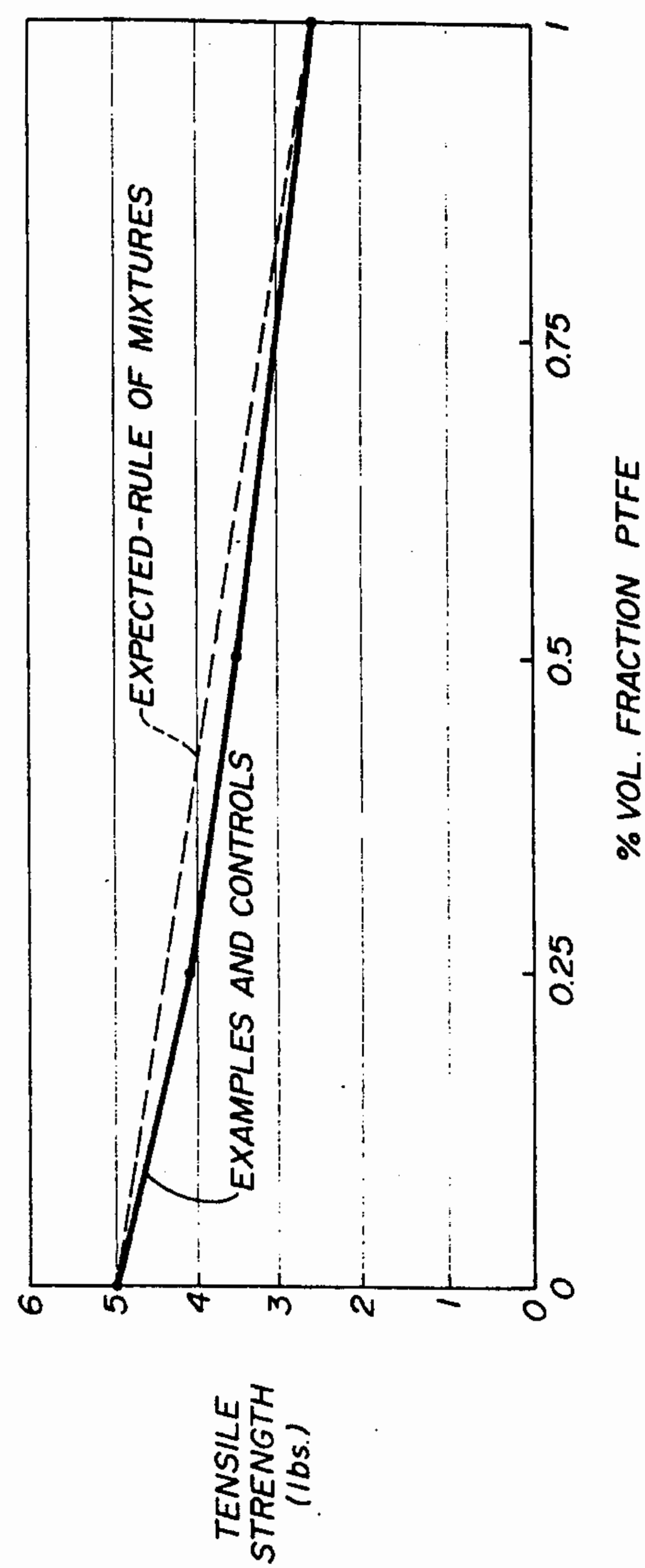
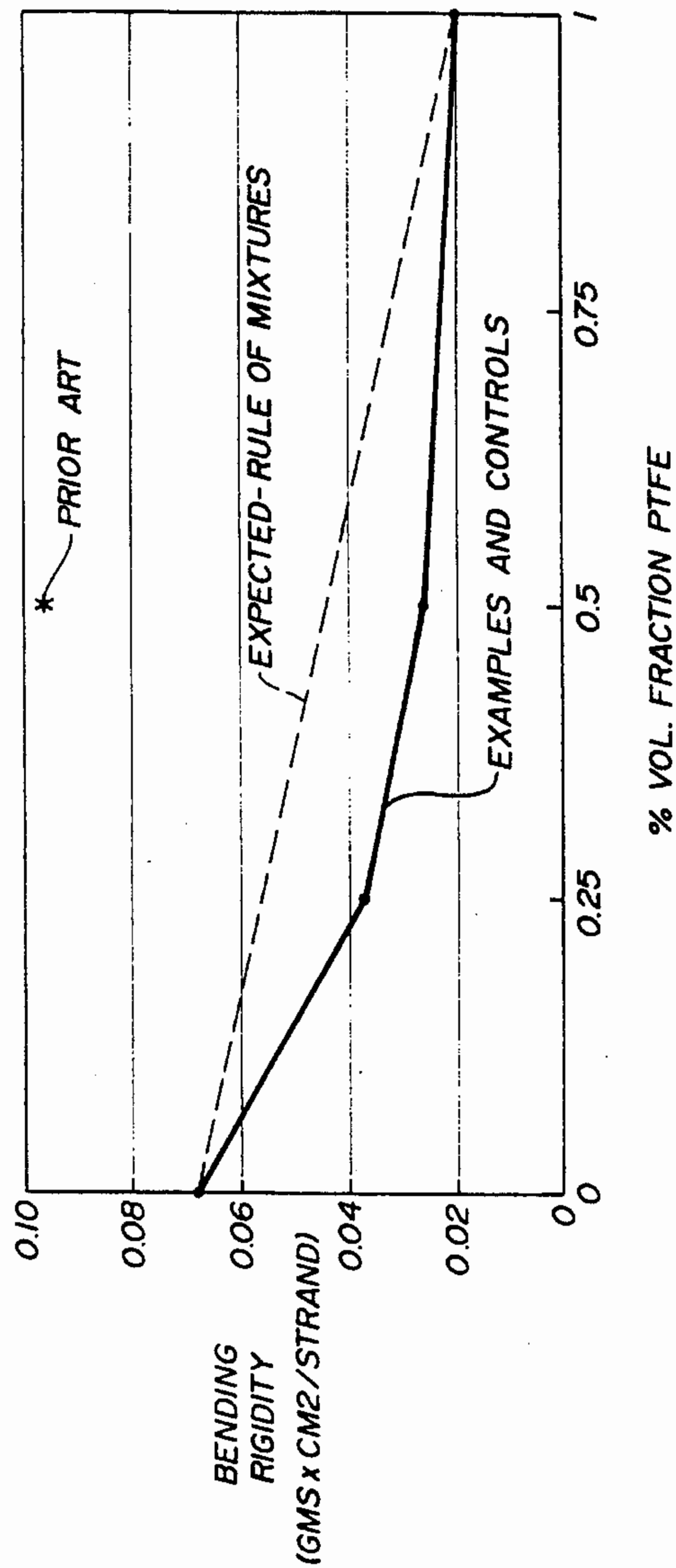

EXPECTED-RULE OF MIXTURES
EXAMPLES AND CONTROLS
TENSILE STRENGTH (lbs.)
% VOL. FRACTION PTFE
0
1
2
3
4
5
6
0.25
0.5
0.75
1

FIG-3


PRIOR ART
EXPECTED-RULE OF MIXTURES
EXAMPLES AND CONTROLS
0.10
0.08
0.06
0.04
0.02
0
BENDING
RIGIDITY
(GMS x CM2/STRAND)
0
0.25
0.5
0.75
1
% VOL. FRACTION PTFE

STERILIZED HETEROGENEOUS BRAIDS

BACKGROUND OF THE INVENTION

This invention relates to braided multifilaments, and especially to sterilized, braided multifilaments suitably adapted for use as surgical sutures or ligatures.

Braided multifilaments often offer a combination of enhanced pliability, knot security and tensile strength when compared to their monofilament counterparts. The enhanced pliability of a braided multifilament is a direct consequence of the lower resistance to bending of a bundle of very fine filaments relative to one large diameter monofilament. However, for this enhancement to be realized, the individual multifilaments must be able to bend unencumbered or unrestricted by their neighboring filaments. Any mechanism which reduces this individual fiber mobility, such as simple fiber-fiber friction, a coating which penetrates into the braid interstices, or a melted polymer matrix which adheres fibers together, will adversely affect braid pliability. In the extreme case where the multifilaments are entirely bonded together, the pliability or bending resistance closely approximates that of a monofilament.

Unfortunately, the prior art abounds with attempts to improve specific properties of multifilament braids at the expense of restricting the movement of adjacent filaments which make up the braid,. For example, multifilament sutures almost universally possess a surface coating to improve handling properties.

U.S. Pat. No. 3,942,532 discloses a polyester coating for multifilament sutures. The preferred polyester coating is polybutilate, which is the condensation product of 1,4-butanediol and adipic acid. U.S. Pat. No. 4,624,256 discloses a suture coating copolymer of at least 90 percent ϵ-caprolactone and a biodegradable monomer, and optionally a lubricating agent. Examples of monomers for biodegradable polymers disclosed include glycolic acid and glycolide, as well as other well known monomers typically used to prepare bioabsorbable coatings for multifilament sutures.

An alternative to the use of the commonly accepted coating compositions for multifilament sutures to improve handling properties is disclosed in U.S. Pat. 3,527,650. This patent discloses a coating composition of polytetrafluoroethylene (PTFE) particles in an acrylic latex. Although the PTFE particles act as an excellent lubricant to decrease the surface roughness of multifilament sutures, the particles have a tendency to flake off during use. Also, this particular coating is a thermoset which requires a curing step for proper application.

More recently, a dramatic attempt has been made to create a monofilament-like surface for a multifilament suture. U.S. Pat. No. 4,470,941 discloses the preparation of "composite" sutures derived from different synthetic polymers. The composite suture is composed of a core of low melting fibers around which are braided high melting fibers. Because of the lack of cohesiveness of the dissimilar fibers, the low melting fibers in the core are melted and redistributed throughout the matrix of the braided, high melting fibers. Although these composite sutures represent an attempt to combine the best properties of different synthetic fibers, it unfortunately fails in this respect due to increased stiffness (as evidenced by FIG. 3 which is described in detail below), apparently due to the reduction of fiber mobility resulting from the fusing of the fibers together.

Another attempt to enhance the properties of multifilament sutures can be found in WO 86/00020. This application discloses coating an elongated core of a synthetic polymer having a knot tenacity of at least 7 grams/denier with a film-forming surgical material. The film-forming surgical material can be absorbable or nonabsorbable, and can be coated on the elongated core by solution casting, melt coating or extrusion coating. Such coated multifilament sutures suffer from the same deficiencies which plague conventionally coated multifilament sutures.

All of the attempts described in the prior art to improve braid properties have overlooked the importance of fiber-fiber friction and its impact on fiber mobility and braid pliability. The properties of concern here include the fiber-fiber frictional coefficients (which frequently relate to the polymer's surface energy), the fiber cross-sectional shape and diameter, and the braid structure which influences the transverse forces across the braid. If fibers composed of highly lubricous polymers are used in the traditional manner, then a highly pliable braid can be prepared. However, in most cases, these braids will be relatively weak and unusable. Hence, a tradeoff between braid strength and pliability exists in the design of conventional braided multifilaments.

In view of the deficiencies of the prior art, it would be desirable to prepare multifilament sutures exhibiting improved pliability and handling properties. More specifically, it would be most desirable to prepare braided multifilaments composed of dissimilar fiber-forming materials in which the fiber-forming materials contribute significantly to enhanced pliability for the braided multifilament without appreciably sacrificing its physical properties.

SUMMARY OF THE INVENTION

The invention is a heterogeneous braid comprising a first and second set of continuous and discrete yarns in a sterilized, braided construction. At least one yarn from the first set is in direct intertwining contact with a yarn from the second set.

Each yarn from the first set is composed of a plurality of filaments of a first fiber-forming material, and each yarn from the second set is composed of a plurality of filaments of a second fiber-forming material.

Surprisingly, the heterogeneous braids may exhibit a combination of outstanding properties attributable to the specific properties of the dissimilar fiber-forming materials which make up the braided yarns. The dissimilar fiber forming materials do not require melt bonding or any other special processing techniques to prepare the heterogeneous braids of this invention. Instead, the integrity of the braid and therefore its properties is due entirely to the mechanical interlocking or weaving of the individual yarns. In fact, it is possible to tailor the physical and biological properties of the braid by varying the type and proportion of each of the dissimilar fiber forming materials used, as well as adjusting the specific configuration of the braid. For example, in preferred embodiments, the heterogeneous braid will exhibit improved pliability and handling properties relative to that of conventional homogeneous fiber braids, without sacrificing physical strength or knot security.

The sterilized, heterogeneous braids of this invention are useful as surgical sutures or ligatures, as well as for

the preparation of any other medical device which would benefit from its outstanding physical or biological properties.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 illustrates a carrier layout for the preparation of a heterogeneous braid within the scope of this invention;

FIG. 2 is a plot representing the relationship between the tensile strength of heterogeneous and homogeneous braids of polyethylene terephthalate (PET) and PTFE yarns, and the volume fraction of PTFE yarns in the braids; and

FIG. 3 is a plot representing a relationship between the initial bending rigidity of heterogeneous and homogeneous braids of PET and PTFE yarns, and the volume fraction of PTFE yarns in the braids.

DETAILED DESCRIPTION OF THE INVENTION

For purposes of describing this invention, a "heterogeneous" braid is a configuration composed of at least two sets of dissimilar yarns mechanically blended by intertwining the dissimilar yarns in a braided construction. The yarns are continuous and discrete, so therefore each yarn extends substantially along the entire length of the braid and maintains its individual integrity during braid preparation, processing and use.

The heterogeneous braids of this invention can be conventionally braided in a tubular sheath around a core of longitudinally extending yarns, although such a core may be excluded, if desired. Braided sheath sutures with central cores are shown in U.S. Pat. Nos. 3,187,752; 4,043,344; and 4,047,533, for example. A core may be advantageous because it can provide resistance to flattening, as well as increased strength. Alternatively, the braids of this invention can be woven in a spiral or spiroid braid, or a lattice braid, as described in U.S. Pat. Nos. 4,959,069 and 5,059,213.

The dissimilar yarns of the first and second set of yarns are braided in such a manner that at least one yarn from the first set is directly intertwined with, or entangled about, a yarn from the second set. Direct mechanical blending of individual, dissimilar yarns therefore occurs from the interweaving and interlocking of these dissimilar yarns, enhancing yarn compatibility and the overall physical and biological properties of the heterogeneous braid. Preferably, every yarn from the first set is in direct intertwining contact with a yarn of the second set to achieve the maximum degree of mechanical blending of the dissimilar yarns.

The first and second fiber-forming materials which make up the filaments of the first and second set of yarns, respectively, can be any materials capable of being spun into continuous filaments. Advantageously, the fiber-forming materials are nonmetallic.

The preferred fiber-forming materials are synthetic fiber-forming polymers which are melt or solution spun through a spinneret to prepare continuous filaments. The filaments so prepared are advantageously stretched to provide molecular orientation and annealed to enhance dimensional stability and/or biological performance. The fiber-forming polymers can be bioabsorbable or nonabsorbable, depending on the particular application desired. Examples of monomers from which bioabsorbable polymers are derived include, but are not limited to, some hydroxyacids and lactones, e.g. glycolic acid, lactic acid, glycolide, lactide, p-dioxanone,

ε-caprolactone and trimethylene carbonate, as well as copolymers and polymer blends derived from these monomers and others. Interestingly, numerous bioabsorbable heterogeneous braids exhibiting varying useful biological properties, such as breaking strength retention in vivo and the absorption profiles in vivo, can be prepared for specific applications by using different combinations of bioabsorbable polymers.

Preferably, the continuous filaments which make up the first and second set of yarns are derived from nonabsorbable polymers. In a preferred embodiment, the first set of yarns acts as lubricating yarns to improve the overall pliability, or compliance, and surface lubricity of the heterogeneous braid. Preferably, the fiber-forming material of the first set exhibits a surface energy (which frequently relates to surface lubricity) less than about 38 dyne/cm, as measured by contact angle of liquids on polymer surfaces, as described by Kissa, E., "Handbook of Fiber Science and Technology," Vol. II, Part B, Marcel Decker, 1984. Such fiber forming polymers include perfluorinated polymers, e.g. PTFE and fluorinated ethylene/propylene copolymers (FEP) and perfluoroalkoxy (PFA) polymers, as well as non-perfluorinated polymers such as polyvinylidene fluoride (PVDF), polyethylene/tetrafluorethylene copolymers (PETFE), the polycholorofluoroethylene polymers, polypropylene (PP) and polyethylene (PE). More preferably, the first fiber-forming material exhibits a surface energy less than about 30 dyne/cm. The preferred polymers for the first set are PTFE, PETFE, FEP, PE and PP, and the most preferred fiber forming polymer is PTFE.

In a more preferred embodiment, the lubricating yarns of the first set are mechanically blended with yarns of the second set which act to provide improved strength to the heterogeneous braid. Preferably, the second set of yarns exhibits a yarn tenacity greater than 3.0 grams/denier, more preferably greater than 5.0 grams denier. The preferred yarns are PET, nylon and aramid, and the most preferred yarns are PET.

In the most preferred embodiment, the heterogeneous braid is composed of a first set of PTFE yarns mechanically blended with a second set of PET yarns in a braided configuration. Advantageously, the braided sheath encloses a core of longitudinally extending PET yarns to further improve the overall strength and resistance to flattening of the heterogeneous braid. In this embodiment, the volume fraction of lubricating yarns in the braided sheath and core desirably ranges from about 20 to about 80 percent. A volume fraction of lubricating yarns below about 20 percent will not typically improve the pliability of the braid, and a volume fraction above about 80 percent may adversely affect the overall strength of the braid. The filament fineness for such a heterogeneous braid is preferably less than 10 denier per filament, preferably from about 0.5 to about 5 denier per filament. A more coarse filament may result in a stiffer braid. The preferred individual yarn denier is between 10 and 100 denier.

The heterogeneous braids of this invention can be prepared using conventional braiding technology and equipment commonly used in the textile industry, and in the medical industry for preparing multifilament sutures. For example, the first and second set of yarns can be interwoven as indicated by the plan view of the yarn carrier layout of FIG. 1 for the preparation of a braided multifilament. The individual yarns of the braided sheath feed from spools mounted on carriers 22, 22' and

24, 24'. The carriers move around the closed circular loop 28, moving alternately inside and outside the loop 28 to form the braiding pattern. One or more carriers are continually following a serpentine path in a first direction around the loop, while the remaining carriers are following a serpentine path in the other direction.

In the illustrated embodiment, carriers 22, 22' are travelling around serpentine path 27 in a clockwise direction as indicated by directional arrows 23, and carriers 24, 24' are travelling around serpentine path 29 in a counterclockwise direction as indicated by arrows 25. The moving carriers dispense yarns which intertwine to form the braid. The yarns from all the carriers in a constructed embodiment of FIG. 1 are dispensed upward with respect to the plane of the drawing, and the braid is taken up on a reel located above the plane of the drawing.

In one embodiment, moving carriers 22, 24 dispense yarns of the first set and moving carriers 22', 24' dispense yarns of the second set to form the heterogeneous braid. In a more preferred embodiment, moving carriers 22, 22' dispense yarns of the first set and moving carriers 24, 24' dispense yarns of the second set. This carrier layout provides a braid in which each yarn of the first set is directly intertwined with a yarn from the second set.

Advantageously, as illustrated in FIG. 1, disposed within the center of the loop 28 are carriers 26 which dispense the core yarns of the braid. In the most preferred embodiment of this invention, moving carriers 22, 22' dispense PTFE yarns, moving carriers 24, 24' dispense PET yarns, and core carriers 26 dispense PET yarns.

Numerous additional embodiments are contemplated within the scope of the invention using conventional braiding technology and equipment. For example, the carrier layout can be modified to prepare a braid configuration using from 3 to 28 sheath carriers, with or without any number of core yarns. Dissimilar yarns from the first and second set of yarns can be plied together using conventional techniques before braiding, and in this embodiment, the carriers can dispense identical bobbins of plied yarns composed of individual yarns from the first and second sets. This embodiment not only offers the advantage of inter-yarn mechanical blending, but also the intimate mixing associated with intra-yarn blending.

Similar to the preparation of conventional homogeneous braids, the yarns from which the heterogeneous braids are prepared are preferably nontextured. The yarn tension during braiding is advantageously adjusted so that the yarn elongation for each set of yarns is about equal. The equilibration of yarn elongation may prevent irregularities, for example, "core popping", which is the tendency of core yarns to break through the braided sheath as the braid is bent. The number of picks per inch in the finished braid can be adjusted to balance the tensile strength of the braid with braid quality, e.g. the tendency for core popping and overall braid smoothness.

After the heterogeneous braid is prepared, it is desirably scoured to remove machine oils and lubricants, and any foreign particles. The scoured braid is preferably stretched at a temperature between the glass transition temperature and melting temperature of the lower melting set of yarns. Therefore, the stretching temperature is such that none of the yarns is actually melted. The stretching operation densifies the braid and improves braid smoothness. Afterwards, the braid may be annealed while under restraint to improve dimensional stability, and in the case of absorbable braids, to improve the breaking strength retention in vivo.

If desired, the surface of the heterogeneous multifilament braid can be coated with a bioabsorbable or nonabsorbable coating to further improve the handleability and knot tiedown performance of the braid. For example, the braid can be immersed in a solution of a desired coating polymer in an organic solvent, and then dried to remove the solvent. Most preferably, the coating does not cause the fibers or yarns to adhere to one another increasing stiffness. However, if the surface of the heterogeneous braid is engineered to possess a significant fraction of the lubricous yarn system, the conventional coating may be eliminated saving expense as well as avoiding the associated braid stiffening.

If the surface of the braid is coated, than the coating composition may desirably contain bioactive materials such as antibiotics and growth factors.

The post-treated heterogeneous braid is sterilized so it can be used for a host of medical applications, especially for use as a surgical suture, preferably attached to a needle. The braid can be sterilized using any of the conventional techniques well known in the art. For example, sterilization can be effected by exposing the braid to gamma radiation from a cobalt 60 source. Alternatively, the braid can be sterilized by exposure to ethylene oxide.

In the following examples, the tensile properties and knot security are each determined using an Instron Tensile Tester. The tensile properties, i.e. the straight and knot tensile strength and the percent elongation, are determined generally according to the procedures described in U.S. Pat. No. 4,838,267. The knot security, which provides an indication as to the number of throws required to secure a knot so that it fails to slip before cleanly breaking, is measured by first tieing a conventional square knot around a mandrel, pulling the knot apart on the Instron Tester to observe whether slipping occurs, and if so, then tieing knots with additional throws until 20 out of 20 knots break cleanly without slipping. The bending rigidity, which is the inverse of pliability, is determined using a Kawabata Pure Bending Tester, as discussed in "The Effects of Structure on the Geometric and Bending Properties of Small Diameter Braids", Drexel University Master Thesis, 1991, by Mr. E. Ritter.

The examples are illustrative only, and are not intended to limit the scope of the claimed invention. The types of yarns used to prepare the heterogeneous braid and the yarn geometry can be varied to prepare heterogeneous braids within the scope of the claimed invention which exhibit a combination of outstanding physical or biological properties.

EXAMPLES

Examples I and II describe heterogeneous braids of PTFE and PET yarns. In order to evaluate the relative performance of these braids, two controls are included which represent 100% PET and 100% PTFE braids, respectively. To the extent possible, the yarn materials and processing conditions are identical for the controls and heterogeneous braid examples. In addition, for comparison purposes, a braid is fabricated with identical materials but processed per the prior art U.S. Pat. No. 4,470,941.

CONTROL I

FIBER MATERIALS: An 8×0 PET braid is fabricated, i.e. 8 sheath yarns and 0 core yarns. All yarns are Dupont Dacron PET, 70 denier, 48 filament, type 52 yarn.

PROCESSING: The yarns are wound on braider bobbins per conventional methods, and the bobbins loaded on each carrier of a N.E. Butt 8 carrier braider. Machine settings include: 32 pick gear, 0.009" wire tension springs, and 183 rpm. The braid is aqueous scoured, and hot stretched at 30% draw ratio at 225° C.

CONTROL II

FIBER MATERIALS: An 8×0 PTFE braid is fabricated. All yarns are Dupont Teflon, 110 denier, 12 filament.

PROCESSING: The yarns are wound on braider bobbins per conventional methods, and the bobbins loaded on each carrier of a N.E. Butt 8 carrier braider. Machine settings include: 36 pick gear, no tension springs, and 183 rpm. The braid is scoured and hot stretched per the conditions described in CONTROL I.

EXAMPLE I

FIBER MATERIALS: An 8×0 heterogeneous braid is fabricated, consisting of four PET 70 denier yarns and four PTFE 110 denier yarns. The yarns are identical to that employed in CONTROL I and II. On a volume basis, the braid is 50.3% PET, and 49.7% PTFE.

PROCESSING: Four bobbins of PET yarn and four bobbins of PTFE yarn were wound by conventional means. The PET bobbins were loaded on the clockwise moving carriers of the N.E. Butt 8 carrier braider, and the PTFE yarn bobbins on the counter-clockwise moving carriers. Machine settings include: 32 pick gear, 0.009" tension springs on PET carriers, no springs on PTFE carriers, and 183 rpm. The braid is scoured and hot stretched per the conditions described in CONTROL I.

EXAMPLE II

FIBER MATERIALS: Identical to EXAMPLE I, except that 6 PET yarns and 2 PTFE yarns were used. On a volume basis, the braid is 75.5% PET, and 24.5% PTFE.

PROCESSING: Identical to EXAMPLE I, except that 2 PET bobbins replace 2 PTFE bobbins. All other braider machine settings, scour and hot-stretch conditions are identical to CONTROL I and II and EXAMPLE I.

PRIOR ART I

FIBER MATERIALS: Identical to EXAMPLE I. On a volume basis, the braid is 50.3% PET, and 49.7% PTFE.

PROCESSING: Identical to EXAMPLE I, except that the hot stretch temperature is at 300° C. and for a longer residence time to facilitate melting of the PET fibers.

The properties of CONTROLS I and II, and EXAMPLES I and II, and the PRIOR ART I are summarized in the following Table:

	USP DIAMETER (mils)	TENSILE STRENGTH (lbs)	KNOT STRENGTH (lbs)	BENDING RIGIDITY (gm × cm²)	KNOT STABILITY (# of throws)
CONTROL I	10.68	4.98	3.14	0.0680	4
CONTROL II	9.11	2.58	2.04	0.0196	7
EXAMPLE I	9.71	3.55	2.41	0.0257	5
EXAMPLE II	10.35	4.10	2.67	0.0371	5
PRIOR ART I	8.81			0.0966	

As may be expected, the tensile strengths of the heterogenous braid examples reflect the relative contributions of the individual components. This behavior is said to follow the "rule of mixtures", i.e. the composite property is a weighted average of the component properties. In equation form,

$$P_c=(Vf_a)(P_a)+(Vf_b)(P_b)$$

where P_c is a composite property (such as tensile strength or modulus), P_a and P_b are the properties of the components a and b, and Vf_a and Vf_b are the volume fractions of components a and b. This behavior is clearly observed in FIG. 2, which shows a plot of tensile strength versus volume fraction of PTFE yarns for the Examples and Controls, in relation to the expected plot according to the rule of mixtures.

Surprisingly, the bending rigidity of the heterogeneous braids in EXAMPLES I and II do not follow the rule of mixtures, and show an enhanced bending rigidity relative to the weighted average of its components. This is shown in FIG. 3 as a plot of bending rigidity versus %PTFE in the braids. Bending rigidity is the inverse of pliability, and is obtained by measuring the slope of the *bending moment-radius of curvature* plot of a suture strand in pure bending. Hence lower bending rigidity relates to a more pliable suture, which is a highly desirable property. The mechanism of this enhanced pliability is believed to be internal lubrication of the braid by the "solid lubricant" behavior of the low surface energy PTFE.

U.S. Pat. No. 4,470,941 discloses the preparation of a "composite" suture with a monofilament-like surface made from multifilament yarns. The composite suture is composed of two different synthetic polymer fibers, which is thermally processed to melt one of the fibers to form a continuous matrix. This process was utilized to produce the PRIOR ART I example, the data of which is shown in Table 1 and FIG. 3. It is observed that the melting of the PET fibers significantly increases the braid bending rigidity due to the bonding of the "non-melted" fibers together, hence resulting in a less pliable braid of diminished utility.

What is claimed is:

1. A surgical suture consisting essentially of a heterogeneous braid composed of a first and second set of continuous and discrete yarns in a sterilized, braided construction wherein at least one yarn from the first set is in direct intertwining contact with a yarn from the second set; and

a) each yarn from the first set is composed of a plurality of filaments of a first fiber-forming material selected from the group consisting of PTFE, FEP, PFA, PVDF, PETFE, PP and PE; and

b) each yarn from the second set is composed of a plurality of filaments of a second fiber-forming material selected from the group consisting of PET, nylon and aramid; and

c) optionally a core.

2. The surgical suture of claim 1 wherein the suture is attached to a needle.

3. The surgical suture of claim 1 wherein the first fiber-forming material exhibits a surface energy less than about 38 dynes/cm.

4. The surgical suture of claim 3 wherein the first fiber-forming material exhibits a surface energy less than about 30 dynes/cm.

5. The surgical suture of claim 4 wherein the first set of yarns is PTFE.

6. The surgical suture of claim 5 wherein the second set of yarns exhibits a yarn tenacity greater than 3.0 grams/denier.

7. The surgical suture of claim 6 wherein the second set of yarns exhibits a yarn tenacity greater than 5.0 grams/denier.

8. The surgical suture of claim 1 wherein the second set of yarns is PET.

9. The surgical suture of claim 8 wherein the volume fraction of the first set of yarns in the braided sheath and core ranges from about 20 to about 80 percent.

10. The surgical suture of claim 9 wherein the fiber fineness of the yarns of the first and second sets is less than 10 denier per filament.

11. The surgical suture of claim 1 wherein at least one yarn from the first set of yarns is plied together to a yarn from the second set of yarns.

12. The surgical suture of claim 8 wherein the suture is attached to a needle.

* * * * *

EXHIBIT 2

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

DePUY MITEK, INC., Plaintiff, v. ARTHREX, INC. and PEARSALLS LTD. Defendants.	)	CIVIL ACTION NO. 04-12457-PBS

MEMORANDUM AND ORDER

January 31, 2007

Saris, U.S.D.J.

INTRODUCTION

Plaintiff DePuy Mitek, which specializes in the manufacture of surgical devices, alleges that Arthrex, Inc., and Pearsalls Ltd. (collectively "Arthrex"), two of Plaintiff's competitors, have infringed U.S. Patent No. 5,314,446 ("the '446 Patent"). Broadly, the '446 patent protects a braided surgical suture with two multi-filament yarns made from different materials. Beyond this definition, though, the parties disagree as to two key terms in the '446 Patent.

DePuy Mitek and Arthrex have moved for summary judgment on the issue of infringement. After a Markman hearing, the Court defines the two contested patent terms and **DENIES** without prejudice Plaintiff's motion for summary judgment of infringement and Defendants' motion for summary judgment of noninfringement.

FACTUAL BACKGROUND

1. The '446 Patent

The patent,[1] also known as the Hunter Patent, protects a sterilized heterogeneous braided suture. Claim One recites:

> A surgical suture consisting essentially of a heterogeneous braid composed of a first and second set of continuous and discrete yarns in a sterilized, braided construction wherein at least one yarn from the first set is in direct intertwining contact with a yarn from the second set; and
>
> a) each yarn from the first set is composed of a plurality of filaments of a first fiber-forming material selected from the group consisting of PTFE, FEP, PFA, PVDF, PETFE, PP and PE; and
>
> b) each yarn from the second set is composed of a plurality of filaments of a second fiber-forming material selected from the group consisting of PET, nylon and aramid; and
>
> c) optionally a core

'446 Patent col.8-9 ll.63-68, 1-9 (emphasis added). The construction of the underlined terms "consisting essentially of" and "PE" are disputed.

2. Procedural History

On November 19, 2004, DePuy Mitek filed this "suture suit" against Arthrex, claiming that two of Arthrex's products - FiberWire® and TigerWire® - infringe the '446 patent. It amended its complaint on September 9, 2005 to include similar allegations

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[1]On May 24, 1994, the United States Patent and Trademark Office issued the '446 Patent, which was assigned to to Ethicon, Inc., a New Jersey based medical device company wholly owned by Johnson & Johnson. On August 9, 2004, Ethicon transferred its interest in the '446 Patent to DePuy Mitek, another Johnson & Johnson subsidiary. DePuy Mitek currently owns this patent.

against Pearsalls, the company responsible for manufacturing the materials and braids that ultimately become part of the FiberWire and TigerWire sutures sold by Arthrex.

FiberWire is a surgical suture that is formed by braiding together yarns of ultra high molecular weight polyethylene ("UHMWPE") and yarns of polyethylene terephthalate ("PET"). These yarns are braided together so that they are in direct intertwining contact with one another. The Defendants also add a silicone coating to the braided suture, which, they argue, significantly improves the handleability and pliability of the device. TigerWire, unlike FiberWire, is composed of a UHMWPE filament and a yarn of nylon. In all other material aspects, however, TigerWire is identical to FiberWire.[2] As such, this Court will refer to these products collectively as "FiberWire."

The Defendants argue that they do not infringe the patent because the UHMWPE utilized in the FiberWire suture is different from the "general purpose" PE described in Claim One. Second, the Defendants submit that the coating on the FiberWire suture removes the product from the scope of Claim One of the '446 Patent.

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[2]As part of a motion to strike, the Defendants raise the possibility that TigerWire may be sufficiently dissimilar from FiberWire so as to warrant a separate examination of the two sutures. However, the differences between the two are not relevant to this opinion, although these distinctions may ultimately prove important.

DISCUSSION

1. Claim Construction

In construing a claim, this Court must first "look to the words of the claims themselves...to define the scope of the patented invention." Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed. Cir. 1996) (citation omitted). The language of the patent claims should be given first priority in the patent construction process because "the claims of a patent define the invention to which the patentee is entitled the right to exclude." Phillips v. AWH Corp., 415 F.3d 1303, 1312 (Fed. Cir. 2005) (*en banc*) (quoting Innova/Pure Water, Inc. v. Safari Water Filtration Systems, Inc., 381 F.3d 1111, 1115 (Fed. Cir. 2004)).

Terms in the patent claims "are generally given their ordinary and customary meaning." Vitronics, 90 F.3d at 1582. The Federal Circuit has held that "the ordinary and customary meaning of a claim term is the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention." Phillips, 415 F.3d at 1313 (citations omitted). This "inquiry into how a person of ordinary skill in the art understands a claim term provides an objective baseline from which to begin claim interpretation." Id.

Despite the primary role that the plain meaning of the claim language plays in divining the subject matter of a patent, the

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Federal Circuit has held that the plain language of the patents is best understood when viewed "in the context of the entire patent, including the specification." Id. Courts must examine the terms of the claim in light of the entire patent because

> It is the person of ordinary skill in the field of the invention through whose eyes the claims are construed. Such person is deemed to read the words used in the patent documents with an understanding of their meaning in the field, and to have knowledge of any special meaning and usage in the field. The inventor's words that are used to describe the invention - the inventor's lexicography - must be understood and interpreted by the court as they would be understood and interpreted by a person in that field of technology. Thus the court starts the decisionmaking process by reviewing the same resources as would that person, *viz.*, the patent specification and the prosecution history.

Multiform Desiccants, Inc. v. Medzam, Ltd., 133 F.3d 1473, 1477 (Fed. Cir. 1998).

Therefore, in interpreting a given claim term, the Court should first look to all intrinsic evidence. First, the Court consults the claims themselves, which "provide substantial guidance as to the meaning of particular claim terms." Phillips, 415 F.3d at 1314 (quoting Vitronics, 90 F.3d at 1582). By examining "the context of the surrounding words of the [disputed] claim," an interpreter may properly comprehend and "determin[e] the ordinary and customary meaning of those [disputed] terms." ACTV, Inc. v. Walt Disney Co., 346 F.3d 1082, 1088 (Fed. Cir. 2003).

Second, the Court must properly weigh the "specification

that concludes with the claims." Phillips, 415 F.3d at 1315. Therefore, the claims of a patent "must be read in view of the specification, of which they are a part." Id. (quoting Markman v. Westview Instruments, Inc., 52 F.3d 967, 978 (Fed. Cir. 1995)). As a consequence, the Federal Circuit has opined: "The specification 'is always highly relevant to the claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term.'" Phillips, 415 F.3d at 1315 (quoting Vitronics, 90 F.3d at 1582). Thus, the specifications should guide this Court in its study of the evidence presented by the patent.

Finally, as part of this intrinsic evidence analysis, the Court "should also consider the patent's prosecution history, if it is in evidence." Markman, 52 F.3d at 980. "Like the specification," the Federal Circuit has suggested that "the prosecution history provides evidence of how the PTO and the inventor understood the patent." Phillips, 415 F.3d at 1317. Nevertheless, the Court has cautioned that prosecution histories, unlike other forms of intrinsic evidence, "often lack[] the clarity of the specification and thus [are] less useful for claim construction purposes." Id. (citations omitted).

In contrast to the intrinsic evidence analysis endorsed by the Court in Phillips, extrinsic evidence, "consist[ing] of all evidence external to the patent and prosecution history,

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including expert and inventor testimony, dictionaries, and learned treatises," is less favored in the claim construction analysis. Markman, 52 F.3d at 980 (citing Seymour v. Osborne, 78 U.S. (11 Wall.) 516, 546 (1870)). Although the Court has expressly "authorized district courts to rely on extrinsic evidence," Phillips, 415 F.3d at 1317, the Federal Court warned that such exogenous evidence is "less significant than the intrinsic record in determining 'the legally operative meaning of claim language.'" C.R. Bard, Inc. v. U.S. Surgical Corp., 388 F.3d 858, 862 (Fed. Cir. 2004) (quoting Vanderlande Indus. Nederland BV v. Int'l Trade Comm'n, 366 F.3d 1311, 1318 (Fed. Cir. 2004)). Therefore, the Court has resolved to "emphasize[] the importance of intrinsic evidence in claim construction" because "extrinsic evidence...is unlikely to result in a reliable interpretation of patent claim scope." Phillips, 415 F.3d at 1319.

A. Meaning of "PE"

The parties dispute the proper scope of the term "PE" in the context of the '446 patent. Plaintiff contends that PE includes any polymer formed from a repeating ethylene monomer, including ultra high molecular weight polyethylene. By contrast, the Defendants argue that the term "PE" in the claims refers to general purpose PE, which excludes UHMWPE.

Plaintiff's expert, Dr. Matthew Hermes, provided the

scientific background, which is largely undisputed. PE is formed from repeating units of the monomer ethylene, (CH_2-CH_2). (Pl.'s Markman Br. Ex. 7 at ¶ 6.) PE may be referred to as (CH_2-CH_2)$_n$, where n equals a whole number and indicates the number of repeating monomeric units of ethylene in the polymer. The "molecular weight" of a PE chain is determined by the length of the chain (i.e., how high n is). UHMWPE is composed of the same monomer unit as any other polyethylene chain, but has a longer chain of the repeating ethylene monomer than "low molecular weight" or "medium molecular weight" PE. (Id. at ¶ 7.) In other words, the building block for a suture made from UHMWPE is a very long and heavy PE chain.

Claim One recites that the first yarn is composed of a fiber-forming material "from the group consisting of" seven specific polymers, including PE. The specification is clear that "PE" means polyethylene. '446 Patent col.4 l.27. This claim does not distinguish between kinds of PE possessing different molecular weights. The patentee did not limit the definition of PE. Cf. Pfizer, Inc. v. Teva Pharms. USA, Inc., 429 F.3d 1364, 1373 (Fed. Cir. 2005) (determining that the claim term "saccharide" should not be construed only to include polysaccharides having ten or less monomer units because the claim, like the specifications, did not contemplate such a limited definition).

Plaintiff has also introduced evidence that a person having ordinary skill in the art would understand PE to mean all polymers made from PE. Dr. Hermes opines: "One of skill in the art would have known that 'PE' means 'polyethylene' and means all polymers made from ethylene. PE is the generic name for all types of PE, including ultra high molecular weight PE." (Pl.'s Markman Br. Ex 7 at ¶ 9.) To support Dr. Hermes's opinion, DePuy Mitek points to several technical dictionaries stating that the term PE encompasses all polymers consisting of ethylene monomers, including UHMWPE. For instance, the Encyclopedia of Polymer Science and Engineering states that "polyethylene [is] the 'common (source-based)' name for all polymers made from ethylene." (Pl.'s Markman Br. Ex. 7, Tab B).

The Defendants, however, argue that UHMWPE is a rigid and inflexible synthetic compound that would never enhance the pliability or lubricity of a suture.[3] As one of Arthrex's experts, Dr. Debi Prasad Mukherjee, argues:

> In February 1992, UHMWPE was a well-known, highly specialized fiber material with strength properties that are far superior to those of general purpose PE. Consequently, the two materials are generally used for very different applications and one is not a substitute for the other. It has been my experience that,

[3]Plaintiff has introduced evidence that UHMWPE is lubricious. (See Plaintiff's Ex. 9 at 51:15-55:5). The parties do not clearly explain the difference, if any, between a lubricious material and a stiff material in the context of a suture. Both appear to be related to handleability and pliability.

> generally, when UHMWPE is intended to be included for a specified application, there is a special effort to make that fact known.

(Def.'s <u>Markman</u> Br. Ex. 12.) Although there is evidence that a person of ordinary skill in the art would understand that UHMWPE has different properties from other kinds of PE, Arthrex has introduced no evidence that one of ordinary skill would not understand the term PE to include UHMWPE.

Defendants argue that the prosecution history contains a disclaimer of the polymer UHMWPE, citing extensively to the discussion of the "Burgess reference" in the '446 Patent's history. (Def.'s <u>Markman</u> Br. Ex. 7-8.) The Burgess patent protects a type of braided fishing line that utilizes a high-tensile PE as part of its construction. In response to the rejection by the patent examiner of the suture claims based on the Burgess patent application, the applicant argued:

> One of the most important requirements for a braided suture is that it have outstanding knot strength when a knot is secured on the suture braid. Indeed, this requirement maybe the <u>most important requirement for a braided suture</u>. This is so because the suture knot is what keeps a stitched wound intact.

(DM1000196). (Emphasis in original). The applicant distinguishes Burgess: "In contrast, knot strength is not even mentioned in Burgess." (<u>Id.</u>) The applicant adds: "Some of the braid filaments of the Burgess fishing line are composed of high tensile polythene thread. This thread gives the line <u>minimal</u> stretchability....Although this thread has great strength

properties, it suffers from low elongation and, in turn, poor knot strength properties." (DM1000196). (Emphasis in original). The parties agree that "high-tensile polythene" is the European terminology for UHMWPE.

In overcoming the Burgess reference, the applicant does distinguish the suture from the fishing wire by drawing a distinction between materials used in the invention, pointing out the poor knot strength properties of high-tensile polythene. The Defendants argue that in distinguishing the heterogeneous braided suture from the fishing line composed of UHMWPE, the patentee limited the scope of its patent to ordinary general use PE. (Def.'s Markman Br. 12-13).

Plaintiff responds that the prosecution history is not a clear disclaimer of the UHMWPE. It emphasizes that the patent examiner and the applicant both routinely refer to the "high tensile polythene" described by the British Burgess patent as "polyethylene." (See, e.g., Pl.'s Markman Br. Ex. 3 at DMI000189.) By including "PE" in the list of polymers in the amended claim, Plaintiff contends, the inventors intended to include UHMWPE. Moreover, while the prosecution history does indicate that UHMWPE was not a preferred polymer because of its minimal stretchability, the applicant emphasized the distinction between the uses and purposes of the two devices:

> In view of the dissimilarities in property requirements between sutures and fishing line, there would be no

> incentive for a medical designer who wishes to improve the properties of a braided suture to study the art related to braided fishing lines. Even if he did use the teachings of fishing line art to modify a suture, then he would inevitably design an unacceptable suture.

(Pl.'s Markman Br. Ex. 3 at DMI000196-97.) In light of this language, Plaintiff's argument that there was never a clear disclaimer of UHMWPE is ultimately persuasive. See Andersen Corp. v. Fiber Composites, LLC, Nos. 05-1434, 06-1009, ____ F.3d ____, 2007 WL 188709, at *10 (Fed. Cir. Jan. 26, 2007) (citing Gillette Co. v. Energizer Holdings, Inc., 405 F.3d 1367, 1375 (Fed. Cir. 2005)) ("It is true that we have warned against importing limitations from the specification into the claims absent a clear disclaimer of claim scope.").

Pulling together all of these threads, this Court finds that an ordinary person skilled in the art of science and suture manufacturing looking to the plain language of the claim, the specification, and the prosecution history of the '446 Patent would conclude that "PE," as used in Claim 1, includes all polymers formed from a repeating ethylene monomer, including UHMWPE.

B. Meaning of "Consisting Essentially Of"

The second term disputed by the parties is the transitional phrase "consisting essentially of." Generally, three transitional terms are used in patent claims: (1) "comprising," which is an open term of transition (2) "consisting of," which is

a closed term of transition, and (3) "consisting essentially of," which is a partially open term perched between the extremes of the other two phrases. "In view of the ambiguous nature of the phrase," the Federal Circuit has opined that "consisting essentially of" "has long been understood to permit inclusion of components not listed in the claim, provided that they do not 'materially affect the basic and novel properties of the invention.'" AK Steel Corp. v. Sollac & Ugine, 344 F.3d 1234, 1239 (Fed. Cir. 2003) (quoting PPG Indus. v. Guardian Indus. Corp., 156 F.3d 1351, 1354 (Fed. Cir. 1998).

To determine those "basic and novel properties of the invention," the Court must look at the specification to determine "the goal of the invention as well as what distinguishes it from prior art." AK Steel, 344 F.3d at 1239-40 (holding that a limiting statement in the specification that silicon should not exceed 0.5% was a disclaimer which had an impact upon the meaning of the phrase "consisting essentially of aluminum.") The Court must also look at the prosecution history of a patent to determine whether an unlisted ingredient was excluded from the scope of a "consisting essentially of' claim. PPG, 156 F.3d at 1355.

Construing the "consisting essentially of" language in a patent claim can "at times blur the distinction between the separate steps in an infringement analysis." AK Steel, 344 F.3d

at 1240. Where the specification and/or prosecution history directly speaks to and conclusively answers the question of what constitutes a material effect, the issue may be resolved as a question of law. Id. In some situations, however, whether an additional ingredient materially affects the basic and novel characteristics of a patented invention is a question of fact for a jury. See PPG, 156 F.3d at 1357 (stating that it is the province of the jury to determine whether the iron sulfide had a material affect on the basic and novel characteristics of the patented glass).

The key question of claim construction for this term in Claim One involves discerning the basic and novel properties of the heterogeneous suture. Once this determination has been made, the Court can attempt to resolve the parties' disagreement over whether the surgical coating placed on FiberWire braided suture "materially affects" the basic and novel properties of the suture described by the '446 Patent. AK Steel, 344 F.3d at 1239.

The Defendants submit that this Court should construe the claim term "consisting essentially of" as follows:

> i) The claimed surgical suture excludes additional ingredients that materially affect the basic and novel characteristics of the claimed invention.
>
> ii) The basic and novel characteristics of the claimed invention are a suture having two dissimilar yarns (from the list identified in the claims) braided together to achieve improved handleability and pliability performance without significantly sacrificing its physical properties.

(Def.'s <u>Markman</u> Br. 16.) By contrast DePuy Mitek suggests:

> The 'novel and basic characteristics' of the invention are a heterogeneous braid of dissimilar non-bioabsorbable yarns of the materials claimed, where at least one yarn from the first set is in direct intertwining contact with a yarn from the second set, and the dissimilar yarns have at least some different properties that contribute to the overall properties of the braid. *Consisting essentially of* excludes sutures that contain bioabsorbable materials as the first and second fiber-forming materials.

(emphasis in original) (Pl.'s <u>Markman</u> Br. 8.)

DePuy Mitek's primary argument is that the transitional phrase was inserted to exclude certain bioabsorbable materials in the prior art from the patent claims. The prosecution history demonstrates the "consisting essentially of" language was added by amendment. In the prosecution history, the examiner originally had rejected the claims based on two references - Doddi and Kaplan - which included braids of dissimilar materials. Plaintiff argues it amended the claims to exclude bioabsorbable materials from the first and second fiber-forming materials in order to further distance itself from this prior art.

In response to the examiner's rejection for anticipation by Kaplan, the applicant stated that in Kaplan, the "sheath yarn" was a "biocompatible yarn that is bioabsorbable or semi-bioabsorbable...In one embodiment the sheath yarn could also contain a non bio-absorbable yarn of one or more chemical compositions....<u>Claim 21 as amended does not claim a sheath yarn composed of a bioabsorbable yarn</u>." (DMI 1000259). (Emphasis

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added). Later, the applicant again distinguishes the prior art: "Kaplan does not suggest or disclose combining a first set of nonabsorbable yarns (i.e., PTFE) and a second set of nonabsorbable yarn (i.e., PET). (DM 1000260).[4] Id. Thus the Plaintiff argues there is a clear and express disclaimer of bioabsorbable yarns in the prosecution history. SanDisk Corp. v. Memorex Prods., Inc., 415 F.3d 1278, 1286 (Fed. Cir. 2005).

Defendants contend that the prosecution history does not support this interpretation because the patent specification provides, "The fiber-forming polymers can be bioabsorbable or nonabsorbable, depending on the particular application desired." '446 Patent col.3 ll.63-65 (emphasis added). Still, under the doctrine of prosecution disclaimer, Plaintiff's argument that it clearly disclaimed bioabsorbable yarns to overcome the rejection seems persuasive. Nonetheless, this debate seems largely beside the point because the issue here involves coatings, not bioabsorbable yarns.

The Defendants contend that the invention's primary basic and novel characteristic is that it improves the handleability and pliability of a suture without significantly sacrificing any physical properties of the constituent materials of the device, like strength or knot tiedown. The specifications reveal that

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[4]In addition, the plaintiff pointed out that Kaplan taught that sheath yarns listed in the invention should not be used in sheaths.

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the mechanical braiding of the two dissimilar fibers was intended to enhance the overall pliability of the device. As the "Background of the Invention" section notes, "the enhanced pliability of a braided multifilament is a direct consequence of the lower resistance to bending of a bundle of very fine filaments relative to one large diameter monofilament." '446 Patent col.1 ll.12-15. For this reason, the inventors eschewed "any mechanism which reduces this individual fiber mobility." Id. at col.1 ll.18-19. The specification states that the invention relates to "sterilized, braided multifilaments suitably adapted for use as surgical sutures or ligatures." Id. at col. 1 ll. 6-8. These "[b]raided multifilaments often offer a combination of enhanced pliability, knot security and tensile strength when compared to their monofilament counterparts." Id. at col.1 ll.8-10. The specification points out, "Unfortunately, the prior art abounds with attempts to improve specific properties of multi-filament braids at the expense of restricting the movement of adjacent filaments which make up the braid. For example, multi-filament sutures almost universally possess a surface coating to improve handling properties." Id. at col. 1 ll. 26-31. It continues: "All of the attempts described in the prior art have overlooked the importance of fiber-fiber friction and its impact on fiber mobility and braid pliability." Id. at col. 2 ll. 14-17. Of significance, the specification states:

> In view of the deficiencies of the prior art, it would be desirable to prepare multifilament sutures exhibiting improved pliability and handling properties. More specifically, it would be most desirable to prepare braided multifilaments composed of dissimilar fiber-forming materials in which the fiber-forming materials contribute significantly to enhanced pliability for the braided multifilament without appreciably sacrificing its physical properties."

Id. at col.2 ll, 32-37 (Emphasis added).

Plaintiff argues that increased pliability is a property only of the preferred embodiment, pointing to the passage that states: "For example, in preferred embodiments, the heterogenous braid will exhibit improved pliability and handling properties relative to that of conventional homogeneous fiber braids, without sacrificing physical strength or knot security." Id. at col. 2 ll. 50-67. As shown above, this is a myopic view of the specification, which states throughout that a primary goal of the invention is to achieve enhanced pliability and handleability. The sterilized heterogeneous braids described in this patent seek to achieve a high degree of pliability and handleability by mechanically blending together two dissimilar synthetic yarns.

Therefore, this Court concludes that the basic and novel properties of the suture described in the '446 Patent are: (1) a surgical suture, (2) composed of two dissimilar yarns from the lists in Claim One, (3) where at least one yarn from the first set is in direct intertwining contact with the yarn from the second set, (4) so as to improve pliability and handleability

without significantly sacrificing the physical properties of the constituent elements of the suture.

2. Summary Judgment

As noted previously, both DePuy Mitek and Arthrex have moved for summary judgment on the issue of patent infringement. However, the summary judgment record is a mess because of the multiple motions to strike, each with extensive appendices and confusing briefing. This Court has allowed Arthrex to supplement Dr. Gitis's expert report to correct certain typographical and computational errors. Moreover, DePuy Mitek has launched a Daubert challenge to Defendants' expert report, and it is difficult to figure out the various expert opinions on the affect of the coatings on the accused devices. Accordingly, this Court will deny these cross-motions for summary judgment without prejudice.

ORDER

Plaintiff's motion for summary judgment of infringement is **DENIED** without prejudice (Docket No. 36). Defendants' motion for summary judgment of noninfringement is **DENIED** without prejudice (Docket No. 39).

All parties are ordered to submit a single brief, not to exceed 20 pages, on the summary judgment issue of patent infringement within 60 days in light of the Court's construction of the '446 Patent. The parties shall file no additional motions

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to strike, and there shall be no replies or sur-replies.

PATTI B. SARIS
United States District Judge

EXHIBIT 3

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

DePuy Mitek, Inc. **a Massachusetts Corporation** **Plaintiff,** **v.** **Arthrex, Inc.** **a Delaware Corporation and** **Pearsalls Ltd.,** **a Private Limited Company** **of the United Kingdom,** **Defendants.**	)))))))))))))))	**Civil No. 04-12457 PBS**

Rebuttal Expert Report of Dr. David Brookstein

I. Background Information

1. I previously submitted an expert report in this case on March 3, 2006. I have been asked to opine on certain opinions expressed by Dr. Mukherjee in his report entitled the "Responsive Expert Report of Dr. Debi Prasad Mukherjee Concerning Non-Infringement of U.S. Patent No. 5,314,446 and Other Matters."

2. I have reviewed the "Responsive Expert Report of Dr. Debi Prasad Mukherjee Concerning Non-Infringement of U.S. Patent No. 5,314,446 and Other Matters," the documents referenced in my prior report and those listed in Ex. H attached hereto.

II. Summary of Opinions

3. I disagree with Dr. Mukherjee's opinion that there is no infringement under the doctrine of equivalents, if "PE," as used in the claims of the 446 Patent, is construed not to include UHMWPE.

4. If Dr. Mukherjee is correct regarding the meaning of "consisting essentially of" and the novel and basic characteristics of the invention, it is my opinion that FiberWire's coating does not materially affect the basic and novel characteristics of the suture claimed in the 446 Patent.

5. If Dr. Mukherjee is correct regarding the meaning of "consisting essentially of" and the novel and basic characteristics of the invention, it is my opinion that the nylon in TigerWire does not materially affect the basic and novel characteristics of the suture claimed in the 446 Patent.

6. If Dr. Mukherjee is correct regarding the meaning of "consisting essentially of" and the novel and basic characteristics of the invention, it is my opinion that FiberStick's adhesive does not materially affect the basic and novel characteristics of the suture claimed in the 446 Patent.

7. The reverse doctrine of equivalents does not prevent infringement.

8. I disagree with Dr. Mukherjee that FiberWire's benefits, which Arthrex promotes, are almost exclusively due to the UHMWPE in FiberWire.

III. If PE Is Construed Not to Include UHMWPE, FiberWire Still Infringes Under the Doctrine of Equivalents

9. As I explained in my previous report, if "PE" as claimed in the 446 Patent is construed not to include "UHMWPE," there is infringement under the doctrine of equivalents because the differences between UHMWPE and "PE" are insubstantial. Dr. Mukherjee has expressed opinions to the contrary. But I disagree with him for at least the following reasons.

10. As one basis for his opinion of substantial differences between "PE" and UHMWPE, Dr. Mukherjee opines that the 446 Patent describes the first fiber-forming materials as "lubricous but relatively weak" and alleges that the first fiber-forming materials are different than UHMWPE, which is known to have certain strength properties (Mukherjee Res. Report at 15). I disagree because the 446 Patent does not describe the first fiber forming materials as "lubricous but relatively weak." In fact, it never describes the first fiber-forming materials, including "PE," as

"weak." Rather, in a preferred embodiment, the 446 Patent describes the first fiber-forming materials as acting "as lubricating yarns," but not "weak" yarns (Ex. D at 4:11-12). UHMWPE is consistent with the description of the first fiber-forming materials in the 446 Patent. The 446 Patent describes that, in a preferred embodiment, the first yarns act as lubricating yarns (Ex. D at 4:11-12). PE, including UHMWPE, is a lubricious material (Ex. I at 52:24-53:1). Further, the 446 Patent explains that the first set of yarns may be "non-absorbable polymers" (Ex. D at 4:10-11). UHMWPE is a non-absorbable polymer. The 446 Patent also describes the first set of yarns as being made from fiber-forming materials (Ex. D at 2:45-46). UHMWPE is a fiber-forming material. Therefore, the 446 Patent's description of the first-fiber forming materials is consistent with UHMWPE. Moreover, UHMWPE is consistent with the more general description of the invention, as set forth in column 2, lines 40-63, column 3, lines, 21-28, 40-65, and column 6, lines 50-56. Therefore, I disagree with Dr. Mukherjee's opinion that the 446 Patent describes the first fiber-forming materials as "weak," and I also disagree that the differences between UHMWPE and PE are substantial.

12. I disagree that the 446 patent describes the first fiber-forming materials as "weak," as Dr. Mukherjee states (Mukherjee Res. Report at 15), for additional reasons. Dr. Mukherjee states that the 446 Patent describes the first fiber-forming materials as being "weak." But this is incorrect. For example, the 446 Patent describes PE, which includes UHMWPE, as a first fiber-forming material, and UHMWPE was known to have certain strength attributes, such as tensile strength. Likewise, the 446 Patent describes polypropylene (PP) as a first fiber-forming material, and it is known to have certain strength attributes, namely tensile strength. This is described in the literature. For example, *Marks' Standard Handbook for Mechanical Engineers*, a well known reference, describes polypropylene fibers as having a breaking tenacity of 4.0-7.0 gpd

(Ex. J). Further, U.S. Patent No. 4,413,110 describes certain polypropylene fibers as having a tenacity of at least about 8 gpd (Ex. K at 2:7-11). Also, the *Production and Applications of Polypropylene Textiles* states on page 54 that the breaking tenacity of polypropylene fibers is over 500 $mNtex^{-1}$ (Ex. L). Thus, certain polyethylene and polypropylene fibers are not "weak" in tensile strength. Thus, I disagree with Dr. Mukherjee's statement that the first-fiber forming materials are all "weak."

13. Dr. Mukherjee seems to indicate that the first fiber-forming materials are all necessarily "weak" in tension when compared to the second fiber-forming materials. But this is incorrect because polypropylene fibers, one of the first fiber-forming fibers, were known to have strength on the same order of magnitude of nylon and PET fibers, two of the second fiber-forming materials. For example, *Marks' Handbook* describes polyester fibers, which I read as including PET, as having a breaking tenacity of 4.4-7.8 gpd, and nylon 6,6 fibers as having a breaking tenacity of 4.6-9.2 gpd (Ex. J). Further, the *Production and Applications of Polypropylene Textiles* states on page 54 states that the breaking tenacity of polyester fibers, which I read as including PET, is 350 $mNtex^{-1}$ (Ex. L). Using this information, PP has a breaking tenacity in the range of other well known relatively high-strength fibers such as polyester (PET) and nylon. Further, one fiber manufacturer describes the tensile strength of two first fiber-forming materials, PVDF and PP, as having about the same tensile strength as two of the second fiber-forming materials, nylon and PET. For example, it states that monofilament PVDF has a tenacity of 4.71 gpd, two monofilament polypropylenes have breaking strengths of 3.0 and 4.0 gpd, two monofilament polyesters (which I read as PET) as having a breaking strength of 4.5 or 6.0 gpd, and nylon monofilaments as having a breaking strength of 4.5-6 gpd (Ex. M; see also Ex. N). Consequently, the first fiber-forming materials are not all "weak" in tension in

comparison to the second fiber-forming yarns, and I disagree with Dr. Mukherjee's assertion that they are.

14. As another basis for his opinion of substantial differences, Dr. Mukherjee opines that the differences between the claimed "PE" (if PE does not include UHMWPE) and UHMWPE are substantial because the claimed second fiber-forming materials are "added for strength" and UHMWPE is added to increase FiberWire's strength. I understand that the relevant comparison is between PE and UHMWPE, not between the claimed second fiber-forming materials and UHMWPE. Thus, I am not sure why Dr. Mukherjee is comparing the second fiber-forming materials to UHMWPE. Nevertheless, I disagree with his statement that FiberWire's construction is the opposite of what is described in the 446 Patent. The 446 Patent describes embodiments in which the first set of yarns is lubricous and provides PE as an example of a lubricous yarn (Ex. D at 4:11-12). The UHMW PE in FiberWire is consistent with this description; FiberWire's UHMW PE is lubricous (Ex. I at 52:24-53:1). The 446 Patent also describes embodiments in which the claimed second fiber-forming yarns, including PET, are braided with the claimed first fiber-forming lubricous yarns, including PE, "to provide improved strength to the heterogeneous braid" (Ex. D at 4:33-36). FiberWire is consistent with this description; FiberWire's PET has a different lubricity than UHMWPE and adds improved strength to the FiberWire braid (Ex. I at 53:20-54:5; 46:16-47:5). Accordingly, PET increases certain knot strength properties, namely knot holding strength,[1] of the braid of PET and UHMWPE because it reduces the tendency of the UHMWPE fibers to slip when tied in a knot.

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1 I use the term "knot pull strength" to refer to the force at which a suture having a knot tied in it fails when tested in a tension test (*see, e.g.*, Ex. O). I use the term "knot holding strength" to refer to the force at which a knot fails by slipping, elongating to a certain extent, or breaking, which can be tested generally in a procedure similar to Ex. P, Q. Knot holding strength is an indication of knot security. The 446 Patent describes another exemplary knot security test (Ex. D at 6:36-44).

Thus, because FiberWire's UHMWPE is lubricous and FiberWire's PET imparts strength, FiberWire's construction is not the opposite of that described and claimed in the 446 Patent. Rather, it is consistent with the 446 Patent's teachings.

15. My opinion is supported by Mr. Grafton's testimony regarding the development of FiberWire and by Arthrex's 234 patent. As Mr. Grafton explained, he had developed a suture having a homogeneous braid of UHMWPE (Ex. I at 51:15-17). But he found this UHMWPE braid to be unacceptable because it had poor knot holding strength properties (Ex. I at 45:16-46:15; 50:1-53:7). As Mr. Grafton explained, the poor knot holding strength properties were attributable to UHMWPE being a lubricous material, which causes the knot to slip (Ex. I at 52:24-53:7). To increase the knot holding strength, Mr. Grafton braided UHMWPE with PET (Ex. I at 53:20-54:5; 46:16-47:5). Mr. Grafton tested the UHMWPE and PET braid and found that it had improved knot holding strength properties as compared to the UHMWPE braid (*i.e.*, the heterogeneous braid did not slip like the homogeneous UHMWPE braid) (Ex. I at 54:24-55:1). This type of UHMWPE and PET braid ultimately became FiberWire. Thus, as Mr. Grafton's experience shows, FiberWire is a braid of UHMWPE (a lubricous yarn) with PET, and the PET increases the knot holding strength of the braid. Accordingly, FiberWire's braid is not, as Dr. Mukherjee opines, the opposite of what is described in the 446 Patent.

16. Arthrex's 234 Patent also supports my opinion. According to Mr. Grafton's 234 Patent, UHMWPE, "while much stronger than ordinary surgical suture, does not have acceptable knot tie down characteristics for use in surgical applications" (Ex. R at 1:19-21; Ex. I at 104:9-15). Mr. Grafton defines knot tie down as a strength, namely the "ability to approximate the tissue and hold [tissue] in place through biomechanical forces" in the body (Ex. I at 26:24-27:2). Mr. Grafton's definition of knot tie down is part of what I refer to as knot holding strength.

According to Arthrex's 234 patent, this problem was overcome by braiding UHMWPE with polyester (Ex. R at 2:50-57). As the 234 patent explains, braiding polyester with UHMWPE improves knot tie down characteristics or the "ability to approximate the tissue and hold it in place through biomechanical forces" (Ex. I at 26:24-27:10). Thus, the 234 patent teaches that polyester, which includes materials such as PET, imparts knot tie down or knot holding strength to a braid of UHMWPE and polyester.

17. Dr. Mukherjee further opines that the differences are allegedly substantial between "PE" (if PE does not mean UHMWPE) and UHMWPE, as used in FiberWire, because UHMWPE is what makes FiberWire so strong (Mukherjee Res. Report at 16). I disagree. As explained above, although one might expect that UHMWPE provides certain strength attributes to FiberWire, namely, tensile strength, the PET adds certain strength characteristics as well, including knot holding strength. Notably, Arthrex discarded the idea of using a braid of just UHMWPE because it had poor knot holding strength characteristics, and braided PET with UHMWPE to increase the knot holding strength.

18. In support of his opinion regarding substantial differences, Dr. Mukherjee also performs a function/way/result analysis. I also disagree with this analysis. Dr. Mukherjee states that the "function" performed by the claimed first fiber-forming materials is "to add lubricity with the recognition that these materials will detract from the strength of the resulting suture" (Mukherjee Res. Report at 16). I disagree. The 446 Patent does not describe the function of the claimed first-fiber forming materials as "detract[ing] from strength." I disagree with Dr. Mukherjee's opinions regarding "detract[ing] from strength" for the same reasons that I stated above with reference to his opinions that the 446 Patent describes the first-fiber forming materials as "weak." Further, I disagree that his reference to column 4, lines 42-54, and a

variation of a single embodiment of a PTFE/PET braid is a statement that the first fiber-forming materials are "too weak for most suture applications" (Mukherjee Res. Report at 7). This section of the 446 Patent describes variations of single embodiment and does not discuss the use of the first fiber-forming materials in "most suture applications."

19. Nevertheless, even if Dr. Mukherjee is correct about the "function" of the claimed first fiber-forming materials, UHMWPE, as used in FiberWire, performs the function of adding "lubricity with the recognition that these materials will detract from the strength of the resulting suture." UHMWPE is a lubricous material that adds lubricity to the FiberWire braid (Ex. I at 52:24-53:1). Also, it is recognized that UHMWPE, due to its lubricity, detracts from certain strength characteristics, including knot holding strength (*see above*, Ex. R at 1:19-21; Ex. I at 104:9-15).

20. Although Dr. Mukherjee refers to the "way" and the "result" of the claimed first fiber-forming material, he never defines what they are. For example, Dr. Mukherjee states that the "result obtained by substituting UHMWPE for the first fiber-forming materials is substantially different." But he does not provide his opinion regarding the "result" attributable to the claimed first fiber-forming materials and the "way" the first-fiber forming materials perform their function. Nevertheless, I disagree with his opinion that the "result" of using UHMWPE in FiberWire is limited to increasing strength. It also adds lubricity which enhances other FiberWire properties such as handleability. Also, he seems to attribute all of FiberWire's strength properties to UHMWPE. I disagree with this opinion. PET also contributes to FiberWire's strength properties, namely knot holding strength properties (Ex. R at 1:19-21,29; 2:50-52; Ex. I at 104:9-15). Further, even if FiberWire's function is increasing tensile strength,

it is my opinion that the first fiber forming materials, such as PP, function to add tensile strength. Therefore, the differences are insubstantial.

21. Dr. Mukherjee disagrees with my opinion regarding equivalents because it is too broad. I believe that he misunderstands my opinion. My equivalency opinion is limited to nonbioabsorbable yarns as the first-forming material.

IV. Under Dr. Mukherjee's Definition of "Consisting Essentially Of," FiberWire Infringes Claims 1, 2, 8, 9, and 12 of the 446 Patent

22. As I understand the law, because the 446 Patent claims recite the phrase "consisting essentially of," if FiberWire has structure in addition to the structure listed in the 446 Patent claims, there is infringement, unless the additional structure materially affects the "basic and novel characteristics" of the claimed suture. Dr. Mukherjee opines that the "basic and novel characteristics" of the suture claimed in the 446 Patent are "a suture having two dissimilar yarns braided together to achieve improved handleability and pliability performance without significantly sacrificing its physical properties" (Mukherjee Res. Report at 18, Section VI.D.). According to Dr. Mukherjee, FiberWire's coating, TigerWire's nylon visual marker strand, and FiberStick's adhesive, each provide a "material" affect on this novel and basic characteristic that precludes infringement (Mukherjee Res. Report at 22, 30, 31). I disagree with Dr. Mukherjee's opinion and address each of his three points below.[2]

[2] Mr. Grafton's testimony and Arthrex's 234 patent support my opinion regarding the equivalence of UHWMPE and PE if "PE" is defined not to include UHMWPE as well as my opinion that there is no material affect on the novel and basic characteristics as set forth in my previous report for the reasons set forth herein. For example, they show that the differences are insubstantial because UHMWPE provides lubricity and PET provides knot holding strength.

A. If the Novel And Basic Characteristics Have The Definitions Provided By Dr. Mukherjee, FiberWire's Coating Does Not Materially Affect Them

23. According to Dr. Mukherjee, the novel and basic characteristics are "a suture having two dissimilar yarns braided together to achieve improved handleability and pliability performance without significantly sacrificing its physical properties" (Mukherjee Res. Report at 18). Dr. Mukherjee opines that FiberWire's coating materially affects this novel and basic characteristic. I disagree for the following three reasons: (i) FiberWire was specifically engineered to have the properties described in the 446 Patent; (ii) the 446 Patent does not consider coating of the type used on FiberWire to have a "material" affect on the basic and novel characteristics; and (iii) Dr. Mukherjee's tests are flawed or inconclusive. I describe each of these three points below.

1. FiberWire Was Engineered to Have The Basic and Novel Characteristics, and the Coating Does Not Materially Affect Them

24. FiberWire's coating does not materially affect FiberWire's characteristics of having two dissimilar yarns (*i.e.*, UHMWPE and PET) braided together to achieve improved handleability and pliability performance without significantly sacrificing physical properties. Both before and after the coating is applied to FiberWire, FiberWire has two dissimilar yarns (*i.e.*, UHMWPE and PET). Further, regardless of the coating, the UHMWPE and PET braid provides improved handleability and pliability performance without significantly sacrificing physical properties. The coating does not prevent or materially affect the two materials from being dissimilar, from being braided, or from forming a braid with improved handleability and pliability performance without significantly sacrificing physical properties. In other words because FiberWire still obtains the handleability/physical property benefits of the UHMWPE/PET braid after the coating is applied, the coating does not materially affect the novel and basic characteristics. FiberWire's coating is merely a surface "lubricant" (Mukherjee Res. Report at Ex. 16).

25. My opinion that FiberWire's coating does not materially affect FiberWire's PET and UHMWPE yarns from being dissimilar, from being braided, or from forming a braid with improved handleability and pliability performance without significantly sacrificing physical properties is supported by Arthrex's development and testing of FiberWire. Arthrex and Pearsalls had originally developed a suture having a homogeneous 100% UHMWPE braid. But they found it to have unacceptable knot holding strength properties (Ex. I at 52:24-53:7). The homogeneous UHMWPE braid was too lubricous to "hold a knot" (Ex. I at 45:16-46:15; 50:1-53:7). At the same time, Arthrex found that the same braided UHMWPE suture had other good "strength" properties (Ex. I at 46:7-8). I consulted with Dr. Hermes and, based on his opinion and because UHMWPE fibers are lubricous (Ex. I at 52:24-53:1), the UHMWPE braid would also have had some good handling properties including surface frictional properties, such as tactile feel. Also, the lubricous yarns would contribute to braid pliability because they allow the fibers to slide past each other when bent. Arthrex and Pearsalls also developed sutures having homogeneous polyester braids (Ex. S). According to Mr. Grafton, Arthrex found them to have lower knot pull strength than a braid of UHMWPE fibers and polyester fibers (Ex. S; Ex. I at 81:8-12). Thus, Arthrex thought that sutures having braids of UHMWPE and braids of polyester each had different drawbacks. Ultimately, Mr. Grafton braided UHMWPE with PET, which is a polyester, and found that the heterogeneous braid had improved knot holding strength properties; it did not slip like the UHMWPE braid he had made:

> Q. And was the knot slippage of this ultra-high molecular weight polyethylene poor security because of the lubricity of polyethylene?
> A. Yes.
> Q. Yes?
> A. Yes.
> Q. So then you came up with the idea to braid PET with the ultra-high molecular weight polyethylene to

reduce the knot slippage?
A. Yes.
Q. And when you say knot slippage, we're referring to this knot security test?
A. Yes.
Q. So are we using the terms knot slippage and knot security interchangeably here?
A. You are, yes.
Q. In your testimony?
A. Yes.
Q. So the knot security of the 100 percent ultra-high molecular weight polyethylene was poor, the prototype; right?
A. Yes.
Q. And your idea was to add the PET and to improve the knot security?
A. I've lost count, it's been so many times, but the answer again is yes.

(Ex. I at 53:2-54:5) (objections omitted). This type of UHMWPE and PET braid was ultimately marketed as FiberWire. Thus, Arthrex engineered a braid of UHMWPE and PET to maximize the benefits of the dissimilar yarns (Ex. I at 68:25-70:13). For example, UHMWPE in FiberWire's braid contributes to the braid's tensile strength, knot pull strength, pliablity, and lubricity/handling, and PET contributes to the braid's knot holding strength, and handling/pliability. Thus, Arthrex designed FiberWire to be braid of dissimilar yarns that has improved handleability and pliability performance without significantly sacrificing physical properties. Although FiberWire is coated, it is still a braid of dissimilar yarns having these benefits. Although the coating may enhance certain suture properties, the coating does not materially affect the fact that FiberWire has a braid with improved handleability and pliability performance without significantly sacrificing physical properties.

26. My opinion that FiberWire was specifically designed to have the novel and basic characteristics that Dr. Mukherjee attributes to the 446 Patent is further supported by other aspects of FiberWire's development. For example, during FiberWire's initial development, Mr.

Grafton asked Pearsalls to "build a 25% Dyneema/75% polyester *blend* in a size 2 that is *very flexible* (like the existing suture or the Ethicon sample)" (Ex. HH) (emphasis added). As Mr. Grafton stated, "[i]f we can get this blend correct, we will have a terrific advancement" (Ex. HH). According to Mr. Grafton, Arthrex varied the dissimilar braid materials in type and amount in order to optimize FiberWire's properties:

> Q. I would like to know what you mean by in your letter when you said, "If we can get this blend correct." You asked them for a 25 percent Dyneema/75 percent polyester blend in Size 2 that's very flexible. And then you said, "If we can get this blend correct, we will have a terrific advancement." What did you mean by "If we can get this blend correct"?
>
> A. The optimization of the two materials. If you had the knot strength, loop security, and tensile strength, as well as the tactile feel of the suture all superior to what was on the market, then it would be a superior product.
>
> Q. Wait a second. You said optimization of two materials.
>
> A. (Witness nods head affirmatively).
>
> Q. At this point in time, November 1998, were you trying to vary the amount and type of the Dyneema and polyester in the braid in order to get the best properties?
>
> A. During -- during the -- during that period of time, yes.
>
> Q. So you were balancing off the properties of each material to try to get the optimum properties --
>
> A. Tensile strength.
>
> Q. To get the optimum tensile strength?
>
> A. (Witness nods head affirmatively).
>
> Q. What about knot security?
>
> A. Yes.
>
> Q. Okay. So you were varying the amount and type of the materials to get the optimum knot security, optimum tensile strength?
>
> A. Yes.
>
> Q. Any other properties? Knot tiedown?
>
> A. The slideability of the knot, the tactile feel in the surgeon's hands of the material.
>
> Q. So you were varying type and proportion of the

materials to optimize all these properties in the product?
A. Yes.

(Ex. I at 68:25-70:13). Further, as explained by Ms. Holloway, FiberWire was braided, so that the individual materials contribute to FiberWire's handleability:

Q. What materials contribute to the handleability of Arthrex's FiberWire sutures?
A. All materials used.

(Ex. T at 31:23-25). Thus, in designing FiberWire to have a dissimilar yarn braid, Arthrex specifically designed FiberWire to have the basic and novel characteristics that Dr. Mukherjee attributes to the 446 Patent: (i) a dissimilar yarn braid having the benefits of each yarn; and (ii) improved handleability and pliability without significantly sacrificing physical properties. Although FiberWire is coated, it still reaps the benefits of this dissimilar yarn braid in terms of handleability/pliability and physical properties. Therefore, the coating does not materially affect the novel and basic characteristics as defined by Dr. Mukherjee.

27. My opinion that FiberWire's coating does not materially affect FiberWire's PET and UHMWPE yarns from being dissimilar, from being braided, and from forming a braid with improved handleability and pliability performance without significantly sacrificing physical properties is further supported by the fact that FiberWire has a very small amount of coating. In fact, it is so small that Pearsalls and Arthrex consider it unmeasureable (Ex. U at 119:5-9; Ex. V at 94:2-9; Ex. W at 48:1-50:16; Ex. X at ARM2104). I have personally observed and studied Pearsalls' coating processes for FiberWire during an inspection of Pearsalls' facilities in January 2006. FiberWire is coated by passing a braid of PET and UHMWPE, which has been dyed[3] and scoured, through a bath of NuSil Med 2174 polymer and Xylene solvent at a rate of 20 meters

3 Most FiberWire is dyed blue. But some, such as TigerWire is not. Also, TigerWire has a braid that includes a Nylon marker band in place of one PET yarn.

per minute (Ex. U at 88:4-9; 82:14-18). Xylene is not a coating. Rather, Xylene is a solvent that dissolves the Med NuSil polymer, so that it can adhere to the FiberWire braid (Ex. U at 87:25-88:3; Video of Pearsalls' manufacturing). After passing through the solution, the coated FiberWire is passed through pads, which are compressed together, to wipe away excess coating (Ex. U at 97:1-18). Further, FiberWire is passed through a five-stage oven that dries the coating and evaporates the solvent (Ex. U at 95:14-17). The process is then repeated. I have measured the amount of coating by weight on FiberWire by determining the linear density (*i.e.*, grams/unit length) of a sample that was not coated, a sample that had been coated once, and sample that had been coated twice (DM Exhibits 284, 342, and 285). I determined that the linear density of Ex. 284 (uncoated) is 2393 denier, Ex. 342 (coated once) is 2474 denier, and Ex. 285 (coated twice) is 2508 denier using a traditional Mettler balance housed at the Philadelphia University Research Center Materials Evaluation Laboratory. Accordingly, the linear density of Ex. 342 indicates a 3.4% pick-up of coating material from the uncoated Ex. 284. The linear density of Ex. 285 indicates a 1.4% pick-up of additional coating material from Ex. 342. Thus, the total pick-up of Ex. 285 over Ex. 284 is approximately 4.8%. The result of this coating process is that, although FiberWire has a very small amount of coating, FiberWire still has two dissimilar yarns braided together to form a braid with improved handleability and pliability performance without significantly sacrificing physical properties. In other words, the coating did not transform the braided FiberWire materials into another structure or cause it to lose its characteristics that are attributable to the dissimilar yarns being braided. For example, the coating is not applied in a very thick layer and then melted together with the yarns to form a non-braided structure. As Arthrex explains in its instructions for use, FiberWire's coating is just a "lubricant" (Mukherjee Res. Report at Ex. 16).

28. My opinion that FiberWire's coating does not materially affect FiberWire's PET and UHMWPE yarns from being dissimilar, from being braided, and from forming a braid with improved handleability and pliability performance without significantly sacrificing physical properties is supported by both my visual observations of FiberWire, as well as those by CETR. Both my photographs and CETR's show that, even at extreme magnifications, it is difficult to even see coating in certain areas of the suture. In fact, both sets of pictures show that FiberWire has fibers that retain their morphological attributes, so that they can contribute to the handleability, pliability, and physical properties of FiberWire.

29. Dr. Mukherjee opines that the SEM's attached to my expert report are "too unclear to draw any conclusions from them" (Mukherjee Res. Report at 30). But Dr. Mukherjee concludes based on these SEM's that the "coating has permeated into the braid" (Mukherjee Res. Report at 30). I do not understand how Dr. Mukherjee can say the SEM's are "too unclear to draw any conclusions" then make conclusions from the very same "unclear" micrographs.

30. I note that Dr. Mukherjee does not opine on the issue of whether FiberWire's coating materially affects the fact that it has a dissimilar yarn braid with improved handleability and pliability without significantly sacrificing physical properties. Rather, he seems to opine that FiberWire's coating affects certain individual properties. But that is not the relevant issue even as he defined the novel and basic characteristics. Rather, the relevant issue as he framed it was whether FiberWire's coating materially affected FiberWire from being a suture with "two dissimilar yarns braided together to achieve improved handleability and pliability performance without significantly sacrificing its physical properties" (Mukherjee Res. Report at 18). In my opinion, because FiberWire is specifically designed to have precisely these characteristics and its

coating is essentially a surface lubricant, FiberWire's coatings effects are not material to the novel and basic characteristics.

2. Based on the 446 Patent, FiberWire's Coating Does Not Materially Affect the Novel and Basic Characteristic

31. In order to determine whether an effect on the basic and novel characteristics, as those terms are defined by Dr. Mukherjee, is "material," I have consulted the 446 Patent to determine what it considers "material" or not "material." In other words, I have considered whether FiberWire's coating is "material" in the context of the invention described in the 446 Patent. Based on the 446 Patent's description of the invention and its description of coatings, FiberWire's coating does not "materially" affect the novel and basic characteristics, as defined by Dr. Mukherjee.

32. My opinion that FiberWire's coating does not have a "material" effect is based on the 446 Patent's explanation that "coating" is not "material" to the invention. As the 446 Patent explains, the direct intertwining braid of dissimilar materials provides "outstanding properties attributable to the specific properties of the dissimilar fiber-forming materials which make up the braided yarns" (Ex. D at 2:50-52). The 446 Patent further explains that such a braid can be further improved with a coating (Ex. D at 6:5-21). Thus, because the 446 Patent specifically contemplates applying coatings of the type used in FiberWire to refine certain braid properties, the 446 Patent does not consider coatings, of the type applied to FiberWire, to have a "material" effect on the basic and novel characteristics of the suture claimed in the 446 Patent.

33. I disagree with Dr. Mukherjee's opinion that FiberWire's coating has a "material" effect because he basically *excludes* coated sutures from the 446 Patent claims (Mukherjee Res. Report at 22). But this is just contrary to the teachings of the 446 Patent. As the 446 Patent describes, the inventors specifically contemplated preferred embodiments having coatings:

> If desired, the surface of the heterogeneous multifilament braid can be coated with a bioabsorbable or nonabsorbable coating to ***further*** improve the handleability and knot tiedown performance of the braid. For example, the braid can be immersed in a solution of a desired coating polymer in an organic solvent, and then dried to remove the solvent. ***Most preferably***, the coating does not cause the fibers or yarns to adhere to one another increasing stiffness. However, if the surface of the heterogeneous braid is engineered to possess a significant fraction of the lubricous yarn system, the conventional coating ***may be*** eliminated saving expense as well as avoiding the associated braid stiffening.

(Ex. D at 6:5-18) (emphasis added). Thus, the inventors specifically *included* coatings within the description of the invention, not *excluded* them, as Dr. Mukherjee opines. Therefore, because the 446 Patent specifically contemplated coatings, such as that used in FiberWire, it is my opinion that FiberWire's coating cannot be deemed to have a "material" effect on the basic and novel characteristics of the invention.

34. My opinion that FiberWire's "coating" does not have a "material" effect is further supported by the fact that Arthrex and Pearsalls did precisely what the 446 Patent teaches to obtain the basic and novel characteristics that Dr. Mukherjee attributes to the suture claimed in the 446 Patent. The 446 Patent teaches forming a heterogeneous braid which has a first and a second set of continuous and discrete yarns (Ex. D at 2:40-41). FiberWire's UHMWPE and PET are braided in a heterogeneous braid and are continuous and discrete yarns. The 446 Patent teaches braiding a lubricous yarn with a yarn of different lubricity (Ex. D at 4:11-12; 4:33-40). Arthrex and Pearsalls do that; they braid UHMWPE, a lubricous yarn, with PET, a yarn of different lubricity. The 446 Patent teaches braiding dissimilar yarns in direct intertwining contact (Ex. D at 2:43-44). Arthrex and Pearsalls braided PET and UHMWPE yarns in direct intertwining contact (Ex. V at 107:5-8). The 446 Patent teaches that each yarn has a plurality of filaments (Ex. D at 2:45-48). FiberWire's braided UHMWPE and PET yarns each have a plurality of filaments, as shown in Exs. E-G attached to my first report and CETR's images. The 446 Patent teaches braiding yarns to obtain the benefits of each. Arthrex and Pearsalls do that as

is shown by its product development (Ex. I at 68:25-70:15). The 446 Patent teaches "to tailor" the physical braid properties "by varying the type and proportion of each of the dissimilar fiber forming materials used" (Ex. D at 2:59-61). Arthrex did just that by trying different types and amounts of UHMWPE and polyester (Ex. I at 68:25-70:15). The 446 Patent teaches coating the braid by immersing it in a solution of a coating polymer and a solvent (Ex. D at 6:9-10). Likewise, Pearsalls and Arthrex coat by passing FiberWire through a coating solution (see above). The 446 Patent specifically contemplates that coating can "***further***" improve the handleability of the suture (Ex. D at 6:5-18) (emphasis added). According to Dr. Mukherjee, FiberWire's coating further improves handleability (Mukherjee Res. Report at 22-23). The 446 Patent states a preference that coating does not adhere the yarns or fibers to one another thereby increasing stiffness (Ex. D at 6:11-13). As shown by the SEM's of the FiberWire, the fibers are not bonded together (Mukherjee Res. Report at Ex. 20 and Exs. E-G). Thus, because Arthrex and Pearsalls specifically engineered FiberWire to be a nonabsorbable heterogeneous braid, as is precisely described in the 446 Patent, the effects of FiberWire coating can hardly be considered material.

35. I further disagree with Dr. Mukherjee's focus on FiberWire's coating with reference to defining what is "material" because the 446 Patent is not about "coating" or eliminating "coatings." Rather, the problem addressed by the 446 Patent is how to improve multifilament braided suture properties. For example, the 446 Patent explains that some prior art attempted to improve braided multifilament suture properties at the expense of restricting the movement of adjacent filaments (Ex. D at 1:26-29). The 446 Patent then provides some prior art attempts including a certain polyester coating for multifilament sutures (Ex. D at 1:32-43), a PTFE coating (Ex. D at 1:43-54), a monofilament like surface on a multifilament braid (Ex. D at 1:55-

3:2), and an elongated core (Ex. D at 2:3-13). According to the 446 Patent, these techniques could be improved upon because they did not focus on improving multifilament properties by increasing fiber-to-fiber mobility (Ex. D at 2:14-17). Thus, the 446 Patent is not saying that coating was a problem that had to be solved. Rather, the 446 Patent is teaching that certain coatings and other techniques were insufficient *by themselves* to sufficiently improve certain multifilament suture properties.

36. As a solution to the issue of improving multifilament braided suture properties, the 446 Patent teaches braiding dissimilar fiber-forming materials in direct intertwining contact to form a heterogeneous braid, that has properties "attributable to the specific properties of the dissimilar fiber-forming materials" (Ex. D at 2:40-53). The 446 Patent also states that certain properties of the dissimilar yarn braid can be "improved" by a coating (Ex. D at 6:5-21). Thus, the solution to the issue of improving multifilament braid properties provided by the 446 Patent is to braid dissimilar fiber-forming yarns in direct intertwining contact. Thus, coatings were not material to the issue addressed by the 446 Patent, nor the solution provided. Therefore, the 446 Patent's description of the invention shows that it does not consider coating, as used on FiberWire, to have a "material" effect on the basic and novel characteristics of the claimed suture.

3. To The Extent That I Understand Dr. Mukherjee's Tests, They Are Irrelevant or Inconclusive

a) Dr. Mukherjee's Tests Are Irrelevant

37. I note that Dr. Mukherjee opines that "coating materially affects handleability," "knot security and knot strength" (Mukherjee Res. Report at 22 and 27). But he never opines on whether the coating materially affects the basic and novel characteristic that he attributes to the 446 Patent, namely two dissimilar yarns braided together to achieve improved handleability and pliability performance without significantly sacrificing physical properties. According to Dr.

Mukherjee, FiberWire's coating affects certain individual suture properties. But the novel and basic characteristics that he attributes are not just individual suture properties. Rather, they are the benefits of braiding dissimilar yarns to improve one property (*e.g.*, handleability) without significantly sacrificing others (*e.g.*, physical properties). As explained above, FiberWire's braided construction has these benefits. Accordingly, any purported affect by FiberWire's coating cannot be considered material in the context of the invention.

38. Dr. Mukherjee seems to rely on the 446 Patent's statement about preferred embodiments for his rationale that a coating will materially affect the basic and novel characteristics of the invention. But he misstates the statement upon which he relies and therefore incorrectly defines material effects. The 446 Patent states that "in preferred embodiments, the heterogeneous braid will exhibit improved pliability and handling properties relative to that of conventional *homogeneous* fiber braids, without sacrificing physical strength or knot security" (Ex. D at 2:62-66) (emphasis added). Thus, the 446 Patent was discussing improved properties relative to *homogeneous* braids, not relative to *uncoated heterogeneous* braids of dissimilar yarns. Dr. Mukherjee ignores the reference to the homogeneous braid.

b) Dr. Mukherjee's Testing and Analysis Is Flawed

39. Dr. Mukherjee relies on Pearsalls' knot strength data (Mukherjee Res. Report Ex. 25), testing performed by Arthrex (Mukherjee Res. Report Ex. 19), testing performed by CETR (Mukherjee Res. Report Ex. 20), and "drape tests" performed by him and Dr. Burke (Mukherjee Res. Report at 27). I do not have sufficient information to fully analyze all of these tests. For example, I do not have information sufficient to determine whether the only difference between the tested samples was coating, how the samples were manufactured, the parameters of the test specifications, and whether the reported data was the complete data obtained from any and all tests performed. Nevertheless, I have formed opinions to the extent that I can, based on the

limited information with which I have been provided. Also, I note that CETR and Dr. Mukherjee appear to have analyzed and tested only FiberWire size #2 and appear to have applied that analysis without any explanation to all FiberWire products.

(1) Pearsalls' Knot Pull Strength Tests Show No Material Change in Knot Pull Strength

40. Dr. Mukherjee relies on Pearsalls' knot pull strength data summarized in Exhibit 25 to his Responsive Report for his opinion that FiberWire's coating materially affects FiberWire's knot pull strength (Mukherjee Res. Report at 28-29). Exhibit 25 to Dr. Mukherjee's Responsive Report is a listing of the average knot pull strength per batch at the "dye" and "measure" stages. Dr. Mukherjee concludes from this data that the coating causes knot pull strength to materially increase. As I understand the data, the "dye" column is the average knot pull strength of a FiberWire batch that did not undergo the coating process that I observed at Pearsalls, and the "measure" column is the average knot pull strength of FiberWire that underwent the coating processes (Ex. U at 47;1-23 Exs. Y and Z). This data appears to show that, in a significant number of instances, the measured knot pull strength *decreased* from the dye to the measure stage and therefore decreased after coating was applied to the suture. Also, at times, the measured knot pull strength stayed exactly the same. Thus, I do not know how Dr. Mukherjee can conclude from data, a significant amount of which is contradictory, that coating causes an increase in knot pull strength. He provides no explanation for this contradiction. Also, it is not clear why he necessarily attributes the change in knot pull strength to be due to coating. He fails to consider the inherent differences in tying knots, which can affect results, manufacturing differences between the "dye" and "measure" samples, and the known large variability in testing textile properties. Mr. Hallet from Pearsalls even explained that variations in the data, which Dr. Mukherjee relies upon, can be due to testing differences, not the material, and the variations in

the data were not really variations (Ex. U at 244:4-6; 348:22-349:6). To the extent that Dr. Mukherjee is relying on the final "average" computed in Ex. 25, that is improper.

41. I further disagree that Dr. Mukherjee can conclude from Pearsalls' knot pull strength data that FiberWire's coating materially affects FiberWire's knot pull strength (Mukherjee Res. Report at 28-29) because he ignores entire sections of relevant data. Pearsalls' normal practice is to perform knot pull strength testing at three stages of manufacturing, namely, the "dye," "intermediate," and "measure" stages. But Dr. Mukherjee wholly ignored the "intermediate" test stage data. The "intermediate" test stage data shows some of the flaws in his analysis. I understand that the suture that is tested during the "intermediate" and "measure" stage has not had any change in materials or undergone different processing (Ex. U at 348:5-13). Therefore, the knot pull strength should not change for a given batch between the "intermediate" and the "measure" stages. But, as summarized in Exhibit AA, Pearsalls' testing shows that the measured knot pull strength was generally not the same at the intermediate and measure stages. Because Pearsalls measured "differences" in knot pull strength between the "intermediate" and "measure" stages, when one would have expected it to stay the same, it would not be correct to conclude that there was in fact a change in knot pull strength between the "intermediate" and "measure" stages. Likewise, absent some explanation, it is not correct to conclude that the knot pull strength is "changing" between the "dye" and "measure" stages. Rather, Pearsalls' tests show that the knot pull strength basically stays the same before and after coating and that variations are probably due to testing differences, such as how the knot was tied. In fact, Mr. Hallet was asked why, for some batches, the average knot pull strength stayed about the same between the "dye" and "measure" stages, but went up at the "intermediate" stage (Ex. U at 341:16-344:25; Ex. BB). Mr. Hallet stated that the differences were probably due to the "operator" or the way the knot

was tied (Ex. U at 343:3-12). Also, Mr. Hallet testified that some changes were not really changes and were considered "about the same" (Ex. U at 344:22-25; Ex. CC). Further, when asked why, for one batch, the average knot pull strength went from 14.83 at the "intermediate" stage to "16.87" at the measure stage, Mr. Hallet attributed it to the "operator" (Ex. U at 346:21-347:1). Further, after reviewing the variations in some batches between the dye, intermediate, and measure stages, Mr. Hallet concluded that the data does not really show any variations in average knot pull strength:

> Q Well, if you look at the testing you cannot really say -- are they all within the tolerance of the testing so that you cannot really say that one of these values is greater than the other?
> A Yes.
> MR. BONELLA: That's correct
> A Yes.

(Ex. U at 348:22-349:6) (objection omitted). Thus, based on my review of Pearsalls' data and Mr. Hallet's explanation of the source of the data, I disagree with Dr. Mukherjee's opinion that he can conclude from the data in Exhibit 25 to his report that FiberWire's coating increased FiberWire's knot pull strength. If anything, Pearsalls' data show that FiberWire's coating has no material effect on knot pull strength.

(2) Arthrex's "Knot Tiedown" Test Is Inconclusive

42. With respect to Arthrex's "knot tiedown" test (Mukherjee Res. Report at Ex. 19), I am unable to draw any definitive conclusions from these tests because Dr. Mukherjee has not provided information about specifically which samples were tested. Also, with respect to Arthrex's "knot tiedown" test, I believe the test is not proper for the reasons expressed by Dr. Hermes.

(3) CETR's Tests Are Flawed and Inconclusive

43. Dr. Mukherjee relies on the CETR tests. But the CETR report does not explain what was tested other than "two new spools of US 2 FiberWire sutures from the law firm, one coated and the other uncoated." Without further information about the construction, manufacturing, processing, and handling of the samples, I cannot completely comment on the CETR tests. Further, the testing methodology is not completely clear from the CETR report. Thus, I cannot fully comment on the tests that CETR conducted.

44. Even assuming that the only difference between the two tested samples is coating, the tests are also inconclusive for the following reasons. Dr. Mukherjee uses the CETR "pliability test" to determine the effect of coating on pliability. But the "pliability test" described in section 5 of the CETR report, and the data derived from this test, are flawed for at least three reasons: (i) the purported "pliability" test uses a *tensile* test to imply pliability; (ii) the "pliability" test incorrectly assumes that *multifilament* FiberWire acts as a *monofilament*; and (iii) the "pliability" assumes a circular cross-section and a constant diameter of the suture. I address each of these errors below.

45. The test described in section 5 of the CETR report is a *tensile* test in which the FiberWire samples were not bent; it is not a *bending* test. It is basic mechanical and textile engineering that tensile tests generally cannot be used to determine bending properties in and of themselves. Typically, a tensile test places a sample in tension by extending it to a given strain level and measuring the dependent variable, tension. In contrast, a typical bending test applies a bending moment to a specimen, measures the amount of deflection in response to the bending moment, and determines from this data a bending modulus or bending rigidity. A tensile test can be used to determine the bending modulus only in the unique circumstance when the material that makes up the specimen's tensile and compressive moduli are equal and the material is monolithic, such

as certain monofilaments. By using a tensile test to determine bending rigidity, CETR assumes that coated FiberWire's tensile and compressive moduli are equal and uncoated FiberWire's tensile and compressive moduli are equal. Neither CETR nor Dr. Mukherjee provided any basis for this assumption. Without testing to prove that this assumption is correct or an explanation as to why it can be assumed, the "pliability" tests conducted by CETR are flawed.

46. The second reason the CETR "pliability" test is flawed is because it incorrectly assumes that *multifilament* FiberWire is a *monofilament*. CETR used the test method advanced in the Rodeheaver paper (Mukherjee Res. Report at Ex. 13) to determine FiberWire's pliability. But the mathematical relationship used by Rodeheaver to determine pliability assumes that the tested suture is a *monofilament* (Mukherjee Res. Report at Ex. 13 at 528). By assuming a monofilament structure, CETR simplistically assumes that a multifilament suture's pliability can be determined by measuring the tensile modulus, measuring suture diameter, and determining the moment of inertia of the suture. But FiberWire is a *multifilament* suture. To determine the bending rigidity of a multifilament textile structure, such as a suture, using the Rodeheaver equation is erroneous. It is well known in the textile field that a multifilament structure's bending rigidity is proportional to the number of filaments, the modulus of elasticity, the fiber-to-fiber mobility and *the individual moment of inertia of each filament.*[4] In other words, the fiber-to-fiber mobility of the multifilament structure will affect the effective structural moment of inertia. Therefore, the Rodeheaver equation cannot be used to determine the pliability for FiberWire.

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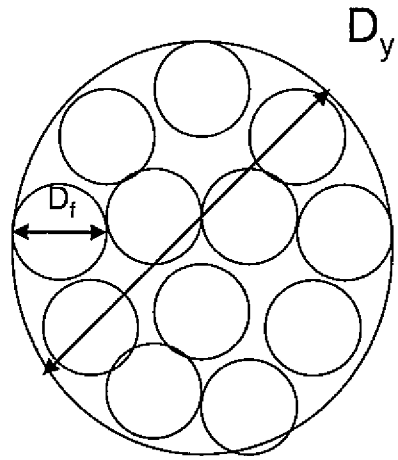
4 *Mechanics of Elastic Performance of Textile Materials, Part XIV: Some Aspects of Bending Rigidity of Singles Yarns*, Platt, M., Klein, W. and Hamburger, W., Textile Research Journal, August 1959 pp. 611-627 (Ex. DD).

47. To understand the errors in Dr. Mukherjee's analysis, consider three example structures and how their bending strength or pliability can be determined. First, consider a monofilament of constant material (and assuming an equal compressive and tensile moduli) and cross-sectional circular shape ("monofilament"). The Rodeheaver test is applicable to such a monofilament structure. Second, consider a multifilament which has total freedom of inter-fiber movement during bending ("multifilament"). Such a multifilament's bending properties can be understood with reference to the 1959 seminal paper by Platt, Klein and Hamburger (Ex. DD). As Platt et al. describe, for a multifilament having complete freedom of fiber movement the product of the bending modulus (E) and the moment of inertia (I) of a yarn is proportional to $N_f E_f I_f$ where N_f refers to the number of individual fibers, E_f refers to the individual fiber modulus, and I_f refers to the moment of inertia of an individual fiber. Third, consider a multifilament that does not have total freedom of inter-fiber movement during bending. The monofilament and multifilament (having complete fiber mobility) can be considered two extreme conditions with the multifilament not having complete freedom of fiber movement being between the other two conditions. Because FiberWire's structure is a braided multifilament, there cannot be complete freedom of fiber movement.

48. To understand the error in Dr. Mukherjee's analysis, I will contrast a hypothetical monofilament structure with a hypothetical multifilament with complete freedom of inter-fiber movement with reference to the Figure below (each multifilament acts independent of its neighboring filament).



Assume $4*D_f = D_y$. For a monofilament type structure, the moment of inertia would be $\pi D_y^4/64$, which is the equation used by CETR and originally advanced by Rodeheaver. But for a multifilament having 12 fibers and total freedom of movement, as shown in the picture, the moment of inertia is $12*\pi D_f^4/64$. Accordingly, the monofilament's and multifilament's moment of inertia, and therefore their bending rigidity, are not equal. Because FiberWire is neither a monofilament nor a multifilament having complete independent fiber movement, its bending stiffness is somewhere between a monofilament and multifilament structure. Thus, assuming FiberWire is a monofilament, as Dr. Mukherjee and the CETR testing assume, also produces errors.

49. The third reason that I disagree that Dr. Mukherjee can draw conclusions from CETR's "pliability tests" is that CETR incorrectly assumes that the FiberWire samples have a circular cross section and that the diameter of each FiberWire suture is constant and equal to 0.65 mm. (Mukherjee Res. Report at Ex. 20 at 3). The Rodeheaver paper assumes a constant circular cross section. Dr. Mukherjee and CETR do not provide any basis for the assumption that the FiberWire samples have a constant circular cross section. The Rodeheaver paper also assumes a

constant diameter along the linear axis of the tested structure. Dr. Mukherjee and CETR do not provide any basis for the assumption that the tested FiberWire samples have a constant diameter along their linear axis. I have consulted with Dr. Matt Hermes. Based on his experience, he opined that even amongst the same USP size suture, suture diameters vary along their linear axis. I have reviewed the attached summary of Pearsalls' batch records, and they show variation in FiberWire's diameter for sutures made from same batch (Ex. AA). For example, the suture diameter varies between the "dye" (uncoated) and "intermediate" (coated) stages, as well as between the "intermediate" and "measure" stages. Thus, FiberWire varies in diameter, and it was incorrect for Dr. Mukherjee and CETR to assume that it does not. This error in assuming that the diameter is always the same is magnified to the fourth power because, in the monofilament equation used by Dr. Mukherjee, the diameter of the suture is raised to the fourth power (Ex. 20 of Mukherjee Res. Report at 3).

50. I also note that CETR's "pliability test" graph is not an accurate depiction of the tensile stress-strain relationship. CETR uses a non-linear, non-logarithmic scale on the horizontal axis. This distorts the true slope of the data. Also, I am not sure whether CETR reported all of its data in this graph or a portion of the data. I note that the data reported seems to be only part of a stress-strain curve that is obtained from a typical tension test. I know this because Figure 2 does not show the strain to failure of either of the samples.

51. I also disagree with the conclusions that Dr. Mukherjee draws from the "pliability" tests because they appear to be contradicted by his "knot slippage strength tests" and "knot run-down tests." I have consulted with Dr. Hermes and, from what we know about these tests, they are basically a type of tension test, similar to the "pliability" test conducted by CETR. Therefore, the slope of the curve from these tests before slippage or run down should be similar to that

obtained in CETR's "pliability" test. But they are not. During the pliability tests, CETR found that the coated suture had a lower modulus, as shown by its smaller slope (Mukherjee Res. Report at Ex. 20 at 3-4). In contrast, the other two CETR tests report a higher modulus for the coated suture, but it is not clear by how much from the graph and data (Mukherjee Res. Report at Ex. 20 at 5-8). The point being that the tests results are inconsistent. They appear to contradict the conclusions drawn by Dr. Mukherjee from the CETR "pliability" tests. Based on the limited information that I have about the tests, they are either inconclusive or show that coating has no material affect on tensile strength because the variations are due to the testing, not the material.

52. I also disagree with the conclusions that Dr. Mukherjee draws from the "pliability" tests because they appear to be contradicted by Pearsalls' testing. Ex. AA summarizes the results of Pearsalls' tension tests on batches of FiberWire at the "dye," "intermediate," and "measure" stages. Pearsalls found that FiberWire's tensile strength basically stayed the same between the uncoated FiberWire and FiberWire that underwent the coating processes. Although there are some variations in the reported measurements (*i.e.*, the tensile strength appears to go up, down, and stay the same), it is my opinion that these are really just an artifact of the testing (*i.e.*, operator variations, knot tying, or the expected variations inherent to textile testing) and not true variations (see paragraphs 40-41). I note that Dr. Mukherjee ignores these data in his analysis.

(4) Dr. Mukherjee's "Drape" Test Is Flawed & Inconclusive

53. I have considered Dr. Mukherjee's "drape test." This "test" is overly simplistic and flawed. Dr. Mukherjee states that he performed his drape test by "draping the suture over [his] extended index finger and observing the degree to which the suture conforms to the shape of [his] finger" (Mukherjee Res. Report at 27). First, I do not understand what he means by "conforms to the shape of my finger." Therefore, I cannot fully respond to his statement

because, among other reasons, I cannot tell what he measured. Second, it appears that Dr. Mukherjee is attempting to approximate FiberWire's pliability by determining FiberWire's ability to bend by using his finger as a test rig. But this method is flawed because he did not provide a true cantilever end support. Consequently, there is no defined position as to where FiberWire begins its bending, and no definitive way to determine the degree of bending. Third, diameter affects pliability, and Dr. Mukhejee does not provide any diameter measurements for the samples that he compared. Therefore, based on what I can determine from his report, it is not possible to scientifically compare the pliability of the uncoated and coated FiberWire using this method.

54. I note that Dr. Mukherjee relies on documents that refer to Ethicon and Mitek products in his analysis (Mukherjee Res. Report at 23-24, Mukherjee Res. Report Exs. 14, 15, 17, & 18). I disagree that these documents are relevant to the analysis because they discuss products and coatings that are different than FiberWire. It is my opinion, that the effect of FiberWire's coating on FiberWire cannot be determined with reference to other products.

B. If Dr. Mukherjee Is Correct Regarding The Meaning Of The Novel And Basic Characteristics, TigerWire's Nylon Does Not Materially Affect Them

55. Dr. Mukherjee has opined that TigerWire does not infringe for the same reasons that he expressed regarding FiberWire (Mukherjee Res. Report at 30). I disagree for the reasons stated above with respect to FiberWire.

56. I understand that the differences between TigerWire and FiberWire are that TigerWire is not dyed blue and replaces one PET yarn strand with one black nylon yarn strand. Dr. Mukherjee opines that TigerWire's nylon materially affects pliability (Mukherjee Res. Report at 30-31). I disagree. The purpose of the nylon strand is for visual identification (Ex. V at 74:21-23). It is my opinion that replacing one PET yarn with one nylon yarn does not materially affect

the novel and basic characteristics of the claimed suture because the nylon marker does not prevent or materially affect FiberWire's PET and UHMWPE from being dissimilar, from being braided, or from being braided to have improved handleability and pliability without significantly sacrificing physical properties. I note that Dr. Mukherjee does not opine otherwise. Rather, he seems to opine that the nylon marker affects pliability. He does not address the issue of whether FiberWire's braid of dissimilar yarns with improved handleability and pliability performance without significantly sacrificing physical properties is affected.

57. Dr. Mukherjee states that TigerWire's nylon yarn "make[s] TigerWire stiffer" than FiberWire, and "materially" affects "pliability" (Mukherjee Res. Report at 31). He also states that "nylon 6,6 fibers of the type used in TigerWire are generally more stiff (*i.e.* less pliable) than fibers made of PET, as used in FiberWire and TigerWire" (Mukherjee Res. Report at 30). I again disagree. First, I disagree that generally TigerWire's nylon 6,6 fibers are necessarily stiffer than PET fibers. Dr. Mukherjee cites to his Ex. 26 for the principle that nylon is stiffer than PET. But Ex. 26 shows the comparative characteristics of "unfilled" PET and "molding compound" nylon. These are not the characteristics of fibers made from these polymers. Thus, it is my opinion that it is improper, absent further information, to rely on this molding compound data for fiber properties. Even if it were proper to rely on this data, Ex. 26 shows that PET has a flexural modulus of 350,000 psi to 450,000 psi and that nylon 6,6 has a flexural modulus of 410,000 psi to 470,000 psi. There is a significant overlap in these ranges. Based on this data, it is possible that nylon 6,6 fibers and PET fibers used in FiberWire and TigerWire have substantially the same flexibility. In that instance, the substitution of one nylon fiber for one PET fiber would have no substantial affect on the pliability of the braid. Second, even if the nylon and PET yarns have different flexibility, but the flexibility were still in the range cited in

Ex. 26, it is my opinion that replacing one nylon yarn with one PET yarn would not materially affect the suture's pliability because the two types of material are close enough in flexural modulus as to be essentially indistinguishable in the FiberWire braid. In fact, the one nylon yarn only makes up about 12% of the suture by weight (Ex. EE at ARM 14744).

58. Dr. Murkherjee's opinion that nylon 66 is generally more stiff than polyester is contradicted by *Marks' Standard Handbook for Mechanical Engineers* (Ex. J at Table 2 at p. 6-155). The elastic modulus of nylon 66 fiber ranges from 25 to 50 gpd and the elastic modulus for polyester fiber, which I read to include polyester, ranges from 50-80 gpd. Thus, it is indicated that nylon 66 fiber is *less stiff* than polyester.

59. My opinion that TigerWire's nylon does not materially affect TigerWire's pliability is supported by Arthrex's testimony. My. Dreyfuss from Arthrex testified that TigerWire and FiberWire show "very similar" knot strength, tensile strength, [and] handleability (Ex. V at 76:1-5). Also, Mr. Dreyfuss testified that that the nylon strand had only "minute" effects on the feel of the suture as compared to FiberWire (Ex. V at 75:13).

60. I understand that Dr. Mukherjee relies on a "drape" test comparing FiberWire and TigerWire. My comments and opinions about Dr. Mukherjee's "drape" test above apply here as well. Additionally, I do not understand what Dr. Mukherjee means when his says "to a much greater degree" and the "course [sic] feel would suggest that the addition of the nylon would adversely affect knot tie-down" (Mukherjee Res. Report at 31). Therefore, I cannot really respond to his opinion. Nevertheless, I understand that Dr. Hermes has considered both no. 2 TigerWire and FiberWire. I also understand that he could not determine any significant difference in the stiffness of TigerWire and FiberWire. Again, Dr. Mukherjee provides no diameter measurements for the samples, and diameter can affect pliability.

C. If Dr. Mukherjee Is Correct Regarding The Meaning Of Novel And Basic Characteristics, The Adhesive As Used On Arthrex's FiberStick Product Does Not Materially Affect Them

61. Dr. Mukherjee has opined that FiberStick does not infringe for the same reasons that he expressed regarding FiberWire (Mukherjee Res. Report at 31-32). I disagree for the reasons stated above with respect to FiberWire. Dr. Mukherjee also states that FiberStick's adhesive materially affects "suture" handleability and therefore concludes that the adhesive materially affects the novel and basic characteristics, as he defines them. It is not my opinion that the adhesive materially affects the novel and basic characteristics, as they are defined by Dr. Mukherjee, because about 38 inches of FiberWire does not have adhesive. The adhesive is irrelevant to the portion of FiberStick's that has no adhesive. Because the portion of FiberStick that has no adhesive still infringes, there is no reason to even consider the adhesive.

62. Arthrex's intended use of FiberStick confirms my opinion that the portion of FiberStick that has adhesive is irrelevant to the properties of the portion that has no adhesive. As I understand FiberStick, it is about a 50 inch length of FiberWire that has about 12 inches of its length treated with Loc-Tite (Ex. FF at ARM1495 at 13-2 and Ex. V at 122:1-15). According to FiberStick's design history file, a portion of FiberStick is treated to "allow for suture loading" and for suture passing through cannulated instruments (Ex. GG at ARM7847). Further, according to Arthrex's intended use, once FiberStick has been passed through a cannulated instrument, the portion having adhesive "can then be cut leaving the remaining suture in place to perform repairs" (Ex. GG at ARM7848). In fact, after the Loc-Tite treated portion of FiberStick has been cut and disposed of, Arthrex promotes using FiberStick's untreated "suture" portion in the "fashion identical to that which is currently marketed" (Ex. GG at ARM7850). The remaining suture is simply a FiberWire suture. As Arthrex states, the treated end does not "affect the design" of the suture (Ex. GG at ARM7848) or "change the intended use or

indication" (Ex. GG at ARM7850). The adhesive portion is only for suture placement; it does not affect the remainder of the suture. Thus, Arthrex's intended use for FiberStick confirms my opinion that the adhesive has no material effect on the portion of FiberStick that does not have adhesive.

V. Reverse Doctrine of Equivalents

63. I have been asked to opine on the issue of whether the reverse doctrine of equivalents applies to FiberWire. Based on discussions with counsel, I understand that the reverse doctrine of equivalents applies when an accused product literally contains all the elements of a claim, but the product is so far changed in principle that it performs the function of the claimed invention in a substantially different way. It is my opinion that the reverse doctrine of equivalents does not apply because FiberWire is not so far changed in principle from the suture claimed in the 446 Patent. I disagree that FiberWire is so far changed in principle that it performs the function of the claimed invention in a substantially different way for the reasons explained above with reference to the doctrine of equivalents (*see* Section III).

VI. FiberWire's Success Is Not Due To Just FiberWire's UHMWPE

64. Dr. Mukherjee opines that he disagrees with my opinion that "some of the benefits marketed by Arthrex in selling FiberWire (and TigerWire) are due to the invention claimed in the '446 Patent" (Mukherjee Res. Report at 33). According to Dr. Mukherjee, the "superior aspects of FiberWire touted by Arthrex relate virtually exclusively to the increased strength from UHMWPE" (Mukherjee Res. Report at 34). I disagree with Dr. Mukherjee's statement. Dr. Mukherjee's statement is contradicted by Arthrex's own marketing documents, technical documents, and technical witnesses.

65. I also disagree with Dr. Mukherjee because he ignores all of the benefits advanced by Arthrex in Arthrex's marketing literature. For example, he ignores that Arthrex promotes that

FiberWire's "polyester braided jacket . . . gives FiberWire superior strength" and it promotes FiberWire as a "braided polyblend suture" (Mukherjee Res. Report at Ex. 30). He further ignores that Arthrex touts other properties such as "knot slippage," knot profile" to name a few, which can be attributed to the claimed heterogeneous braid (Mukherjee Res. Report at Ex. 30) for the reasons provided below.

66. Mr. Grafton, developer of Arthrex's FiberWire, testified that the increase in strength of FiberWire is not due to UHMWPE. Mr. Grafton testified that a 100% UHMWPE braided suture was unacceptable because the knot holding strength was too low (Ex. I at 46:7-15; 52:16-20). Mr. Grafton said that the knot holding strength was too low because of the lubricity of the UHMWPE. Mr. Grafton then had the idea of adding PET into the braided structure, so that the PET would increase the knot holding strength (Ex. I at 53:8-11; 54:9-14). It was not until Arthrex braided the UHMWPE with PET that the "polyblend" suture became acceptable (Ex. I at 54:9-55:15).

67. Mr. Grafton also represented to the Patent Office that UHMWPE alone was not acceptable in suture applications because the knot tie down or knot security was too low (Ex. I at 24:18-21; 103:25-104:12; Ex. R). Based on these statements from Mr. Grafton, I disagree with Dr. Mukherjee when he states that "superior aspects of FiberWire touted by Arthrex relate virtually exclusively to the increased strength from UHMWPE." Rather, FiberWire's benefits touted by Arthrex can be attributed at least in part to the invention claimed in the 446 Patent.

68. I reserve the right to comment further on Dr. Mukherjee's analyses and report when more information about the analyses becomes available. I may use trial demonstratives to explain my opinions.

Dated: April 13, 2006

David Brookstein, Sc.D.
Fellow-American Society of Mechanical Engineers

CERTIFICATE OF SERVICE

I certify that the foregoing Rebuttal Expert Report of Dr. David Brookstein was served by Federal Express overnight mail on April 13, 2006 on the following:

Charles W. Saber
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Christopher Weld, Jr.
Todd & Weld LLP
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Boston, MA 02109

Dated: April 13, 2006

Erich M. Falke

EXHIBIT 4

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

DePuy Mitek, Inc. **a Massachusetts Corporation** **Plaintiff,** **v.** **Arthrex, Inc.** **a Delaware Corporation and** **Pearsalls Ltd.,** **a Private Limited Company** **of the United Kingdom,** **Defendants.**	)))))))))))))))	**Civil No. 04-12457 PBS**

<u>Expert Report of Dr. David Brookstein</u>

I. Background Information

A. Teaching Experience

1. I am the Dean and Professor of Engineering at the School of Engineering and Textiles of Philadelphia University. I have held this position since 1994. In 2005, I also was appointed Executive Director of Research at Philadelphia University.

2. I was a Visiting Scholar at the Harvard University Center for Textile and Apparel Research (Division of Engineering and Applied Sciences) between 2002-2003.

3. I was an Adjunct Professor in Mechanical Engineering at Northeastern University in Boston, MA from 1981-1983. At Northeastern, I taught undergraduate courses in statics, dynamics, and mechanics of deformable bodies and material science.

4. I was Assistant Professor of Textile Engineering at Georgia Institute of Technology, College of Engineering from 1975 – 1980. At Georgia Tech, I taught and

conducted research in the fields of textile and composites engineering with special emphasis on improving the energy efficiency of manufacturing systems.

B. Work Experience

5. From 1980 to 1994, I worked at Albany International Research Co. At Albany International Research, I was an Associate Director from 1992 to 1994. From 1983 to 1992, I was an Assistant Director. From 1980 to 1982, I was a Senior Research Associate. While at Albany International Research Co., I directed all activities of the professional engineering group and was responsible for contract research, development, and manufacture of advanced composite materials and technical polymeric materials. My accomplishments include the invention and development of the multilayer interlock braiding system for producing three-dimensionally reinforced fibrous performs for aerospace structures, the development of implantable biomedical devices such as vascular prostheses and orthopedic implants and the development of unique textile-based civil engineering structures.

C. Publications

6. My publications include, among other things:

"Joining Methods of Advanced Braided Composites," Composite Structures, 6, p. 87-95, 1986.

"Structural Applications of Advanced Braided Composites," Proceedings of the SPE Advanced Polymers Composites Division, November 1988.

"Processing Advanced Braided Composite Structures," Proceedings of the WAM of ASME, Materials Division, November 1988.

"Interlocked Fiber Architecture: Braided and Woven," Proceedings of the 35th SAMPE Meeting, April, 1990.

"Evolution of Fabric Preforms for Composites," Journal of Applied Polymer Science: Applied Polymer Symposium, 47, p. 487-500, 1991.

"A Comparison of Multilayer Interlocked Braided Composites with Other 3-D Braided Composites," 3rd International Techtextil Symposium, 14-16, May 1991, Frankfurt.

"On the Mechanical Behavior of 3-D Multilayer Interlock Braided Composites," with Preller, T., and Brandt, J., DASA-Deutsche Aerospace, Proceedings of NASA Fiber-Tex '92.

"The Solid Section Multilayer Interlock Braiding System," 4th International Techtextil Symposium, 4 June 1992, Frankfurt.

"On the Mechanical Properties of Three-Dimensional Multilayer Interlock Braided Composites, TECHTEXTIL Symposium, 1993, Frankfurt.

"3-D Braided Composites-Design and Applications," Sixth European Conference on Composite Materials, 20-24 September 1993, Bordeaux.

"Concurrent Engineering of 3-D Textile Preforms for Composites," International Journal of Materials and Product Technology, Vol. 9, Nos. 1/2/3, 1994.

"Physical Properties of Twisted Structures" with Ning Pan, Fiber Society Symposium, Asheville, NC, 1998.

D. Patents

7. I am an inventor on the following U.S. Patents:

U.S. Patent 4,290,170 - "Device for Aligning and Attenuating Fiber Mats," A device for producing aligned carbon fiber webs for use in composites.

U.S. Patent 4,497,866 - "Sucker Rod," An elliptical cross-section braided composite rod for pumping oil.

U.S. Patent 4,602,892 - "Sucker Rod," A braided composite rod and coupling for pumping oil.

U.S. Patent 4,841,613 - "Pressure Developer or Press Roll Containing Composite Material," A composite press roll with variation of radial stiffness.

U.S. Patent 4,909,127 - "Braiders," A braider with non-circular braider tracks and a unique package carrier for use with braider.

U.S. Patent 5,004,474 - "Prosthetic Anterior Cruciate Ligament Design," An artificial ligament device having a tubular woven ligament and being adapted for joining the ends of two bones.

U.S. Patent 5,357,839 - "Solid Braid Structure" A 3-D system for producing braids.

U.S. Patent 5,358,758 - "Structural Member" A fiber reinforced structural member produced from a complex woven fabric.

U.S. Patent 5,411,463 - "Composite Roll and Method of Making" A fiber reinforced roll for papermaking.

U.S. Patent 5,501,133 - “Apparatus for Making a Braid Structure” A novel manufacturing system for producing 3-D multilayer interlock braided textile and fiber reinforced composite structures.

U.S. Patent 5,697,969 - “Vascular Prosthesis and Method for Implanting” A fibrous synthetic vascular graft with a combination of resorbable and non-resorbable layers.

E. Education

8. I have a Doctor of Science in the field of Mechanical Engineering, Minor Studies in Management from Sloan School of Management, Massachusetts Institute of Technology, 1976.

9. I have a Master of Science in Textile Technology from M.I.T., 1973.

10. I also hold a Bachelor of Textile Engineering, from Georgia Tech, 1971.

11. I also attended the Harvard Business School Summer Program on Research Management in 1990 and the Harvard Graduate School of Education MLE Summer Program, 1998.

12. When I was a researcher at Albany International Research Co., in the late 1980's, I led a program that involved the development of braided sutures for a commercial client. While at Albany, I researched, developed, tested and evaluated numerous braided and woven biomedical implants, including woven ACL prosthesis, braided artificial arteries, and textile-based, resorbable bone plates and screws. Furthermore, I have taught textile engineers at the undergraduate and graduate level at Philadelphia University materials that involve the design, construction, braiding, manufacturing, and processing of textile structures that includes braids. Specifically, among other things, I have taught courses in Fiber Science which include fiber and yarn tensile, bending, and compression properties. Additionally, I was awarded the TechTextil Innovation Prize (Germany) in 1993 for my work in braiding.

13. A copy of my CV is attached under Tab A. A list of my publications and patents are set forth in my CV . Over the past four years, I have been deposed or testified as an Expert Witness in five cases. A complete list of cases in which I have provided testimony within the past four years is attached under Tab B. A list of the documents that I used in forming my opinions is set forth in Tab C.

14. I have been engaged by counsel of DePuy Mitek as a consultant in this litigation at a consulting rate of $300/hour.

II. Summary of Opinions

15. It is my opinion that sales of Arthrex's FiberWire™ and TigerWire™ suture products (in all sizes and regardless of whether it is attached to needle, or any other component)

literally infringe claims 1, 2, 8, 9, and 12 of U.S. Patent No. 5,314,446 (the ‘446 Patent) (Tab D). I understand that Arthrex sells FiberWire™ in the United States as free strands, attached to needles of various sizes, and attached to anchors used in various surgical applications (*e.g.*, rotator cuff repair, shoulder instability procedures). I further understand that Arthrex sells TigerWire™ in the United States attached to needles and anchors. I use the term “FiberWire™ suture products” to refer to all FiberWire™ products regardless of whether they are free strands, attached to needles, or attached to anchors. I use the term “TigerWire™ suture products” to refer to all TigerWire™ products regardless of whether they are sold attached to anchors or needles.

16. It is my opinion that sale of Arthrex’s FiberWire™ and TigerWire™ suture products (in all suture sizes) directly infringes claims 1, 2, 8, 9, and 12 of the ‘446 Patent under the doctrine of equivalents.

17. I understand that Pearsalls imports into, and sells in, the United States unsterile, untipped FiberWire™ and TigerWire™. It is my opinion that such unsterile, untipped products are a component of the invention claimed in the ‘446 patent and constitute a material part of the invention claimed in claims 1, 2, 8, 9, and 12 of the ‘446 patent.

18. It is my opinion that the FiberWire™ and TigerWire™ sutures imported and sold by Pearsalls are especially adapted for use in infringement of claims 1, 2, 8, 9, and 12 of the 446 Patent, and are not a staple article or commodity of commerce suitable for substantial noninfringing use.

19. It is my opinion that some of the benefits of FiberWire™ and TigerWire™ sutures are due to the invention, claimed in claims 1, 2, 8, 9, and 12 of the 446 Patent.

III. Materials Considered in Forming My Opinions

20. I understand that Arthrex has admitted that Pearsalls manufactures the Arthrex FiberWire™ and TigerWire™ suture. (Arthrex’s Response to Mitek Interrogatory #2). I

attended the Pearsalls plant inspection and deposition in Taunton, Somerset, England on January 11, 2006. Mr. Brian Hallet testified on behalf of Pearsalls. While attending the Pearsalls plant inspection, I personally observed the manufacturing processes used to make the braid that comprises the FiberWire™ and TigerWire™ sutures. I may testify about the manufacturing process that I observed on January 11, 2006 at Pearsalls and the explanation of it as set forth by Pearsalls at depositions and in documents. I may use videotape deposition testimony or exhibits made from the videotape to aid me in testifying.

21. The manufacturing process to make the FiberWire™ and TigerWire™ suture braids that I observed includes the following steps: twisting core and sheath yarns, steam setting core and sheath, winding braider bobbins, braiding, winding to skein, scouring, dyeing, stretching, coating, and thermal treating, and subsequent inspection. I also observed Pearsall's testing laboratory. I may testify about each of these processes and the Pearsalls' equipment used in the manufacturing and testing processes. In addition to observing the manufacturing processes, I have also reviewed documents that describe them (DMI Exs. 279, 281, 287-312). I may rely on these documents in testifying about FiberWire™ and TigerWire™.

22. I have reviewed technical documents concerning FiberWire™'s and TigerWire™'s construction and manufacturing. I have also reviewed deposition transcripts of technical witnesses concerning FiberWire™ and TigerWire™, including the depositions of, among others, Arthrex Engineer, Peter Dreyfuss, Arthrex's Vice President of Operations Kevin Grieff, and Pearsalls' Brian Hallet. A list of the documents that I used in forming my opinions is set forth in Tab C.

23. I have examined samples of FiberWire™ and samples of FiberWire™ taken at various stages of the manufacturing processes (DMI Exs. 282, 283, 284, 285, 342 and Bates nos. ARM 25451-52, and ARM 25590).

IV. Legal Framework of My Opinions

I have been told by counsel to apply the following principles of United States Patent law in my analysis.

A. Direct Infringement

24. I understand that the statutory basis for a determination of direct patent infringement is set forth in 35 U.S.C. §271(a) which states:

> Except as otherwise provided in this title, whoever without authority makes, uses, offers to sell, or sells any Patented invention, within the United States or imports into the United States any Patented invention during the term of the Patent therefore, infringes the Patent.

25. I understand that an analysis of direct infringement requires two steps. First, the Court determines the meaning of the claims. Then, the properly construed claims are applied to a product to determine whether it infringes the Patent. I understand there are two types of direct infringement -- literal infringement and infringement under the doctrine of equivalents.

26. Infringement is "literal" when each claim limitation is literally present in a device. I understand that even if a device does not literally have each claim limitation, there is still infringement if the device has an equivalent of the claimed limitation that is not literally present. I understand that one method for determining whether a structure is equivalent to a claim limitation is the insubstantial differences test. Under this test, if the differences between the structure and the claim element are insubstantial, then they are equivalent. One method for determining whether the differences are insubstantial is whether the structure in the accused

device "performs substantially the same function in substantially the same way to obtain the same result" ("function/way/result test") as the claimed element.

V. Direct Infringement

A. Claim Construction

27. As mentioned above, I understand that the first step in an infringement analysis is to construe the claims. I understand that the Court will determine the meaning of the claim terms in the '446 Patent. Until the Court determines the meaning of the claims, I have been asked to assume the meaning of the following claim terms.

"PE" – means all types of polyethylene (PE) including ultra high molecular weight polyethylene.

"consisting essentially of" – means the claimed suture with all of its limitations and any other unlisted materials that do not materially affect the basic and novel characteristics of the claimed suture.

I have been told that the Court will determine the basic and novel characteristics of the claimed invention. I have been asked to assume that the basic and novel characteristics are a heterogeneous braid of dissimilar non-bioabsorbable yarns of the type claimed, where at least one yarn from the first set is in direct intertwining contact with a yarn from the second set, and the dissimilar yarns have at least some different properties that contribute to the overall properties of the braid.

"direct intertwining contact" –means the mechanical interlocking or weaving of the individual yarns that make up the suture braid.

"volume fraction of the first set of yarns in the braided sheath and core" means the ratio of the cross-sectional area of the first set of yarns in the sheath and core to the total cross sectional area of all the yarns in the surgical suture.

I reserve the right to modify my opinion should the Court determine the meaning of the claims are different than the above constructions provided by counsel.

B. Literal Infringement

28. I have been asked to provide my expert opinion regarding whether Arthrex's FiberWire™ and TigerWire™ suture products infringe claims 1, 2, 8, 9, and 12 of the '446 Patent. It is my opinion that Arthrex's FiberWire™ and TigerWire™ suture products infringe claims 1, 2, 8, 9, and 12 of the '446 Patent. It is my understanding that Arthrex has offered for sale or sold each of its FiberWire™ and TigerWire™ suture products within the United States. Therefore, there is literal infringement because, as described below, each of Arthrex's FiberWire™ and TigerWire™ suture products literally has all of the limitations of claims 1, 2, 8, 9, and 12. In determining literal infringement, I first consider the construction of FiberWire™ and TigerWire™. Then, I compare the claims, with the definitions as provided above, to the FiberWire™ and TigerWire™ suture products.

1. Arthrex's FiberWire™ and TigerWire™ Suture Products

29. I understand that all Arthrex's FiberWire™ suture, except size 4-0, is made of a core of polyethylene yarns (of the ultra high molecular weight type) and a braided sheath of polyethylene yarns (of the ultra high molecular weight type) and PET yarns (Dreyfuss 9/16/05 Dep. at 43, 55-57). The braided sheath is made by having one set of carriers, which have polyethylene, traversing the braider bed in a serpentine and clockwise fashion and the other set of carriers, which have PET, traversing the braider bed in a serpentine counter-clockwise fashion. I understand that Arthrex sells only sizes 5, 2, 0, 2-0, 3-0, and 4-0 FiberWire™ (Dreyfuss 9/16/05 Dep. at 31). I understand that the description of FiberWire™ is generally described in Arthrex's 510K for FiberWire™ (DMI Ex. 78 at ARM 001899).

30. I also understand that no. 2 Arthrex TigerWire™ is basically identical to no. 2 FiberWire™ with one exception. TigerWire™ has one black nylon yarn that replaces one of the PET yarns in no. 2 FiberWire™. No. 2 TigerWire™ has 8 yarns of PE, 7 yarns of PET, and 1 yarn of nylon braided together. (DMI Ex. 318) I also understand that Arthrex sells TigerWire™ in only size no. 2 (Dreyfuss 9/16/05 Dep. at 106). I understand that Arthrex also sells a TigerTail™[1] product that "is a version of FiberWire™ suture with a black strand that creates spiral marking along one-half length of the suture" (DMI Ex. 318).

31. I understand that FiberWire™ and TigerWire™ have been made with "Spectra" and "Dyneema" ultra high molecular weight polyethylene yarns in manufacturing the FiberWire™ suture (Dreyfuss Dep. p. 44-45, Grieff Dep. 9/15/05 p. 22-23, and 51). Spectra and Dyneema are trade names for certain companies' ultra high molecular weight polyethylene.

32. Arthrex's FiberWire™ and TigerWire™ suture is coated with NuSil Med-2174 manufactured by NuSil technology. (Dreyfuss 9/16/05 Dep. at 42). NuSil MED-2174 is generally described at DMI Ex. 78 at ARM 1933-36. I also understand that Arthrex sells a FiberStick™[2] product. I understand FiberStick™ to be a 50 inch piece of FiberWire™ that has 12 inches of its length stiffened with Loc-Tite (DMI Ex. 3 and Dreyfuss 9/16/05 Dep. at p. 122).

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[1] Because TigerTail™ includes FiberWire™, TigerTail™ infringes the '446 patent for the same reasons that FiberWire™ infringes.

[2] Because FiberStick™ includes a portion of FiberWire™, FiberStick™ infringes the '446 patent for the same reasons that FiberWire™ does.

2. Arthrex's FiberWire™ and TigerWire™ Suture Products Literally Infringe Claim 1

33. It is my opinion that all of Arthrex's FiberWire™ and TigerWire™ suture products[3] literally infringe claim 1 of the '446 because they literally have all of the limitations of claim 1 as set forth below.

Claim 1 of the '446 Patent	**FiberWire™ and TigerWire™ Suture Products**
A surgical suture consisting essentially of a heterogeneous braid composed of a first and second set of continuous and discrete yarns in a sterilized, braided construction wherein at least one yarn from the first set is in direct intertwining contact with a yarn from the second set; and	The sterilized FiberWire™ and TigerWire™ suture is a braid of polyethylene (PE) and polyester (PET).[4] The PE and PET yarns are both continuous and discrete. The PE and PET are mechanically intertwined so that at least one PE yarn and one PET yarn are braided in direct intertwining contact. (DMI Ex. 318)
a) each yarn from the first set is composed of a plurality of filaments of a first fiber-forming material selected from the group consisting of PTFE, FEP, PFA, PVDF, PETFE, PP and PE; and	The FiberWire™ and TigerWire™ suture is made from PE yarns that are made of a plurality of PE filaments. (Dreyfuss 9/16/05 Dep. at p. 50:21-51:1)

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[3] I understand that Arthrex's FiberWire™ and TigerWire™ suture products include at least the products having the following Arthrex catalog product codes: AR-7200, AR-7201, AR-7202, AR-7203, AR-7204, AR-7205, AR-7205T, AR-7207, AR-7209, AR-7209SN, AR-7209T, AR-7210, AR-7211, AR-7219, AR-7220, AR-7221, AR-7222, AR-7223, AR-7225, AR-7227-01, AR-7227-02, AR-7228, AR-7229-12, AR-7229-20, AR-7230-01, AR-7230-02, AR-7232-01, AR-7232-02, AR-7232-03, AR-7237, AR-7250, AR-7251, AR-1320BNF, AR-1322BNF, AR-1322-75SF, AR-1322-752SNF, AR-1915SNF, AR-1920SNF, AR-1322SX, AR-1322SXF, AR-1324B, AR-1324BF, AR-1324BF-2, AR-1324BNF, AR-1324HF, AR-1324SF, AR-1934BF, AR-1934BF-2, AR-1934BFT, AR-1934BFX, AR-1934BNF, AR-1934BLF, AR-1915SF, AR-1920BF, AR-1920BF-37, AR-1920BFT, AR-1920BN, AR-1920BNF, AR-1920BNP, AR-1920BT, AR-1920SF, AR-1920SFT, AR-1925BF, AR-1925BFSP, AR-1925BNF, AR-1925BNP, AR-1925SF, AR1927-BF, AR-1927BNF, AR-1928SF, AR-1928SF-2, AR-1928SNF, AR-1928SNF-2, AR-2225S, and AR-2226S (DMI Ex. 3). To the extent that I have not recited a specific Arthrex product by name or code, if any unrecited product includes any portion of a FiberWire™ or TigerWire™ suture, it would infringe claims 1, 2, 8, 9, and 12 of the '446 patent for the same reasons stated herein.

[4] Q. And what incoming yarns are received by Pearsalls when Pearsalls manufactures and braids the bulk sutures made for Arthrex's FiberWire™ sutures?
A. Incoming yarns would be ultra high molecular weight polyethylene and PET. (Dreyfuss 9/16/05 Dep. at p. 43:15-19)

b) each yarn from the second set is composed of a plurality of filaments of a second fiber-forming material selected from the group consisting of PET, nylon, and aramid; and	The FiberWire™ and TigerWire™ suture is made from PET yarns that are made of a plurality of PET filaments. (Dreyfuss 9/16/05 Dep. at p. 64:14-17)
c) optionally a core.	Arthrex's FiberWire™ sutures have a core except for 4-0 FiberWire™. (DMI Ex. 318)

34. I understand that Arthrex has contended that it does not infringe claim 1 of the '446 Patent for several reasons. To the extent that I understand these positions, I will address them here. I reserve the right to amend or supplement my opinions based on Arthrex's full explanation of its positions.

35. I understand that Arthrex may contend that its FiberWire™ and TigerWire™ products do not infringe claim 1 because they have a coating of NuSil MED-2174. I further understand that the basis of Arthrex's argument is that the coating materially affects the basic and novel characteristics of the claimed invention. As I understand the argument, I disagree with it.

36. As explained above, I have been asked to assume that the basic and novel characteristics are a heterogeneous braid of dissimilar non-bioabsorbable yarns of the type claimed, where at least one yarn from the first set is in direct intertwining contact with a yarn from the second set, and the dissimilar yarns have at least some different properties that contribute to the overall properties of the braid. The addition of a coating on FiberWire™ and TigerWire™ does not have any material affect on these basic and novel characteristics. Regardless of the coating, FiberWire™ and TigerWire™ both still have a heterogeneous braid of dissimilar non-bioabsorbable yarns of the type claimed, where at least one yarn from the first set is in direct intertwining contact with a yarn from the second set, and the dissimilar yarns have at least some different properties that contribute to the overall properties of the braid. The coating

is non-bioabsorbable and does not materially affect bioabsorbability of the yarns, does not materially affect at least one yarn from the first set being in direct intertwining contact with a yarn from the second set, and the coating does not materially affect each yarn from contributing to the overall properties of the heterogeneous braid. Furthermore, Arthrex documents describe the coating as a lubricant (DMI Ex. 78 at ARM1976).

37. The ‘446 Patent specifically contemplates, in the “Detailed Description of the Invention,” that the braided sutures of the invention can be coated (Tab D at 6:5-21). The ‘446 Patent describes the invention as including applying polymer coatings by making a solution of the polymer and a solvent, immersing the suture in the coating and solvent, and drying the suture (Tab D at 6:9-11). Thus, the ‘446 Patent’s description of the invention as contemplating coatings supports my opinion that FiberWire™’s and TigerWire™’s coatings do not materially affect the novel and basic characteristics of the invention because the inventors specifically contemplated coated sutures. Notably, FiberWire™ and TigerWire™ are coated just as the ‘446 Patent describes; they are immersed in a solution of NuSil MED-2174 and a solvent and dried.[5]

38. Further, I have taken Scanning Electron Micrographs at the Materials Evaluation laboratory at the Philadelphia University Research Center of DMI exhibit 284 (uncoated), DMI exhibit 342 (coated once), and DMI exhibit 285 (coated twice) FiberWire™ suture braids. My Scanning Electron Micrographs are attached at Tabs E (DMI Ex. 284), F (DMI Ex. 342), G (DMI Ex. 285).

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[5] My opinion is further supported because the ‘446 Patent claims a “suture.” I understand that most sutures are coated. Thus, the Patent claims clearly contemplate sutures having coatings, otherwise they would not cover many, if any, sutures.

39. It is my expert opinion and observation from the above Micrographs that the coating on the FiberWire™ suture does not substantially permeate the braided structure and does not reside between the braid yarns.

40. It is my expert opinion and observation that the coating only appears on the surface of the braid.

41. I understand that Arthrex may argue that its FiberWire™ and TigerWire™ suture products do not literally infringe claim 1 because generally at least one end of its FiberWire™ and TigerWire™ suture products are "tipped." I also understand that Arthrex may argue that FiberStick™ does not infringe because about 12 of the 50 inches of its FiberStick™ product is stiffened. With respect to FiberWire™ & TigerWire™, tipping means stiffening the end of the suture with Loc-Tite. (Dreyfuss 9/16/05 Dep at p. 122). To the extent I understand Arthrex's position, I disagree with it.

42. In my opinion, the stiffening and tipping is irrelevant because the remainder of the FiberWire™, TigerWire™, and FiberStick™ suture products are not tipped or stiffened. Thus, at least a significant length of the FiberWire™, TigerWire™ and FiberStick™ suture products infringe. Therefore, regardless of the tipping and stiffening, FiberWire™, TigerWire™, and FiberStick™ infringe for the reasons set forth above.

43. Moreover, it is generally known that multifilament sutures have tipped ends so that they do not fray. Because the claims of the '446 patent are directed to a multifilament suture, it would not make sense for a multifilament suture claim to eliminate almost all multifilament sutures because of such a basic characteristic, *i.e.* tipped ends.

44. As explained above, Arthrex's TigerWire™ is substantially identical to Arthrex's FiberWire™ except that one carrier of PET yarn is replaced with a black nylon strand.

Otherwise, Arthrex's FiberWire™ braid is no different than Arthrex's TigerWire™ braid.[6] I understand that Arthrex contends that its TigerWire™ suture products do not infringe because they have one black nylon strand. To the extent that I understand Arthrex's argument, I disagree.

45. It is my opinion that the nylon marking strand in Arthrex's TigerWire™ suture is non-bioabsorbable and therefore does not materially affect the basic and novel characteristics of the invention in the '446 Patent. For one thing, nylon is expressly mentioned in claim 1 as one of the fiber-forming materials from which the second set yarn can be made. Thus, the inventors contemplated it as being part of their invention, not as changing the basic and novel characteristics of their invention. Further, the inclusion of nylon yarn instead of one yarn of PET (I understand that nylon makes up only 3.4% of TigerWire™ suture, DMI Ex. 318) does not materially affect the basic and novel characteristics of the invention because the braid is still a heterogeneous braid of non-bioabsorbable yarns of the type claimed, at least one yarn of PE is in direct intertwining contact with a PET yarn, and the nylon does not materially affect the yarns from contributing to the properties of the overall braided suture.

46. My opinion is supported by Mr. Dreyfuss' testimony. Mr. Dreyfuss testified on behalf of Arthrex that that the nylon in Arthrex's TigerWire™ suture products is for visual identification and has "minute differences in its feel and strength characteristics" (Dreyfuss 9/16/05 Dep. at p. 75:7-14). Since visual identification is not a basic and novel characteristic, the inclusion of a nylon marker band has no material effect on the basic and novel characteristics of the invention.

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[6] Q. Sure. Sure. Is the braid in any Arthrex
TigerWire™ different than the braid used in Arthrex's No. 2
FiberWire™?
A. The braid, no. (Dreyfuss 9/16/05 Dep. at p. 31, line 24 – p. 32, line 2)

3. Arthrex's FiberWire™ and TigerWire™ Needle Products Literally Infringe Claim 2

47. It is my opinion that all of Arthrex's FiberWire™ and TigerWire™ needle products[7] literally have all of the limitations of claim 2.

Claim 2	Arthrex's FiberWire™ and TigerWire™ needle products
The surgical suture of claim 1 wherein the suture is attached to a needle.	Each FiberWire™ & TigerWire™ suture needle product has a FiberWire™ suture attached to a needle (DMI Ex. 3).

4. Arthrex's FiberWire™ and TigerWire™ Suture Products Literally Infringe Claim 8

48. It is my opinion that all of Arthrex's FiberWire™ and TigerWire™ suture products[8] literally infringe claim 8 of the '446 for the following reasons:

Literal FiberWire™ Structure	Claim 8
The surgical suture of claim 1 wherein the second set of yarns is PET.	Each FiberWire™ and TigerWire™ suture product has PET as a second set of yarns.

[7] Arthrex's FiberWire™ and TigerWire™ needle products includes all Arthrex's products that are sold with a needle attached to a FiberWire™ or TigerWire™ suture including at least the following Arthrex catalog product codes AR-7200, AR-7202, AR-7204, AR-7205, AR-7205T, AR-7207, AR-7211, AR-7219, AR-7220, AR-7223, AR-7225, AR-7227-01, AR-7227-02, AR-7228, AR-7229-12, AR-7229-20, AR-7230-01, AR-7230-02, AR-7232-01, AR-7232-02, AR-7232-03, AR-7250, AR-7251, AR-1320BNF, AR-1322BNF, AR-1322-752SNF, AR-1915SNF, AR-1920SNF, AR-1324BNF, AR-1920BNP, AR-1934BNF, AR-1920BN, AR-1920BNF, AR-1925BNF, AR-1925BNP, AR-1927BNF, AR-1928SNF, and AR-1928SNF-2 (DMI Ex. 3).

[8] I understand that Arthrex's FiberWire™ and TigerWire™ suture products include at least the products having the following Arthrex catalog product codes: AR-7200, AR-7201, AR-7202, AR-7203, AR-7204, AR-7205, AR-7205T, AR-7207, AR-7209, AR-7209SN, AR-7209T, AR-7210, AR-7211, AR-7219, AR-7220, AR-7221, AR-7222, AR-7223, AR-7225, AR-7227-01, AR-7227-02, AR-7228, AR-7229-12, AR-7229-20, AR-7230-01, AR-7230-02, AR-7232-01, AR-7232-02, AR-7232-03, AR-7237, AR-7250, AR-7251, AR-1320BNF, AR-1322BNF, AR-1322-75SF, AR-1322-752SNF, AR-1915SNF, AR-1920SNF, AR-1322SX, AR-1322SXF, AR-1324B, AR-1324BF, AR-1324BF-2, AR-1324BNF, AR-1324HF, AR-1324SF, AR-1934BF, AR-1934BF-2, AR-1934BFT, AR-1934BFX, AR-1934BNF, AR-1934BLF, AR-1915SF, AR-1920BF, AR-1920BF-37, AR-1920BFT, AR-1920BN, AR-1920BNF, AR-1920BNP, AR-1920BT, AR-1920SF, AR-1920SFT, AR-1925BF, AR-1925BFSP, AR-1925BNF, AR-1925BNP, AR-1925SF, AR1927-BF, AR-1927BNF, AR-1928SF, AR-1928SF-2, AR-1928SNF, AR-1928SNF-2, AR-2225S, and AR-2226S (DMI Ex. 3).

	(DMI Ex. 318).

5. Arthrex's FiberWire™ and TigerWire™ Suture Products Literally Infringe Claim 9

49. It is my opinion that all of Arthrex's FiberWire™ and TigerWire™ suture products[9] literally infringe claim 9 of the '446. I have used the following definition of "volume fraction of the first set of yarns in the braided sheath and core" which means the ratio of the cross-sectional area of the first set of yarns in the sheath and core to the total cross sectional area of all the yarns in the surgical suture. For the following reasons, FiberWire™ and TigerWire™ literally infringe claim 9 of the '446 patent for the following reasons:

Claim 9	**Arthrex's FiberWire™ and TigerWire™ Products**
The surgical suture of claim 8 wherein the volume fraction of the first set of yarns in the braided sheath and core ranges from about 20 to 80 percent.	Every Arthrex's FiberWire™ and TigerWire™ construction has a ratio of the cross-sectional area of UHMWPE in the sheath and core to the total cross sectional area of all the yarns in the surgical suture that ranges from 20 to 80 percent. (DMI Ex. 318).

[9] Arthrex's FiberWire™ and TigerWire™ suture products include at least the products having the following Arthrex catalog product codes: AR-7200, AR-7201, AR-7202, AR-7203, AR-7204, AR-7205, AR-7205T, AR-7207, AR-7209, AR-7209SN, AR-7209T, AR-7210, AR-7211, AR-7219, AR-7220, AR-7221, AR-7222, AR-7223, AR-7225, AR-7227-01, AR-7227-02, AR-7228, AR-7229-12, AR-7229-20, AR-7230-01, AR-7230-02, AR-7232-01, AR-7232-02, AR-7232-03, AR-7237, AR-7250, AR-7251, AR-1320BNF, AR-1322BNF, AR-1322-75SF, AR-1322-752SNF, AR-1915SNF, AR-1920SNF, AR-1322SX, AR-1322SXF, AR-1324B, AR-1324BF, AR-1324BF-2, AR-1324BNF, AR-1324HF, AR-1324SF, AR-1934BF, AR-1934BF-2, AR-1934BFT, AR-1934BFX, AR-1934BNF, AR-1934BLF, AR-1915SF, AR-1920BF, AR-1920BF-37, AR-1920BFT, AR-1920BN, AR-1920BNF, AR-1920BNP, AR-1920BT, AR-1920SF, AR-1920SFT, AR-1925BF, AR-1925BFSP, AR-1925BNF, AR-1925BNP, AR-1925SF, AR1927-BF, AR-1927BNF, AR-1928SF, AR-1928SF-2, AR-1928SNF, AR-1928SNF-2, AR-2225S, and AR-2226S (DMI Ex. 3).

6. Arthrex's FiberWire™ and TigerWire™ Needle Products Literally Infringe Claim 12

50. It is my opinion that all of Arthrex's FiberWire™ and TigerWire™ needle products[10] literally have all of the limitations of claim 12.

Claim 12	**Arthrex's FiberWire™ and TigerWire™ Needle Products**
The surgical suture of claim 8 wherein the suture is attached to a needle.	Arthrex's FiberWire™ and TigerWire™ needle products have either a FiberWire™ or TigerWire™ suture attached to a needle. (DMI Ex. 3).

C. Arthrex's FiberWire™ and TigerWire™ Suture Products Literally Infringe Under the Doctrines of Equivalents

51. It is my opinion that all of Arthrex's FiberWire™ and TigerWire™ suture products also infringe claims 1, 2, 8, 9, and 12 of the '446 Patent under the doctrine of equivalents because the differences, if any, between the claims, as I understand they may be construed by Arthrex, and Arthrex's FiberWire™ and TigerWire™ suture products are insubstantial.

52. I understand that Arthrex contends that there is no literal infringement because the claim limitation with respect to the "first-fiber-forming material" is not present because, although FiberWire™ has "PE" or polyethylene, it has one type of "PE," ultra high molecular weight polyethylene (UHMWPE). If it is determined that "PE" as claimed does not mean

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[10] Arthrex's FiberWire™ and TigerWire™ needle products includes all Arthrex's products that are sold with a needle attached to a FiberWire™ or TigerWire™ suture including at least the following Arthrex catalog product codes AR-7200, AR-7202, AR-7204, AR-7205, AR-7205T, AR-7207, AR-7211, AR-7219, AR-7220, AR-7223, AR-7225, AR-7227-01, AR-7227-02, AR-7228, AR-7229-12, AR-7229-20, AR-7230-01, AR-7230-02, AR-7232-01, AR-7232-02, AR-7232-03, AR-7250, AR-7251, AR-1320BNF, AR-1322BNF, AR-1322-752SNF, AR-1915SNF, AR-1920SNF, AR-1324BNF, AR-1920BNP, AR-1934BNF, AR-1920BN, AR-1920BNF, AR-1925BNF, AR-1925BNP, AR-1927BNF, AR-1928SNF, and AR-1928SNF-2 (DMI Ex. 3).

polyethylene (*i.e.*, including UHMWPE), then it is my opinion that there is infringement under the doctrine of equivalents because any differences are insubstantial.

53. I have used the "function/way/result" test to determine infringement of claims 1, 2, 8, 9, and 12 under the doctrine of equivalents. In particular, I have determined the function/way/result of the claim element that Arthrex contends is not literally satisfied and compared that to the function/way/result of UHMWPE in FiberWire™ and TigerWire™.

54. In my opinion, the "function" of the first fiber-forming material is the same as the function of UHMWPE in Arthrex's FiberWire™ and TigerWire™ suture products:

Claims 1, 2, 8, 9, and 12 Limitation	**Function of Limitation Under the Doctrine of Equivalents**	**Function of UHMWPE in FiberWire™ and TigerWire™ Suture Products**
a) each yarn from the first set is composed of a plurality of filaments of a first fiber-forming material selected from the group consisting of PTFE, FEP, PFA, PVDF, PETFE, PP and PE; and	The function of the first set of yarns is to contribute a property that is different than a yarn from the second set.	UHMWPE contributes different lubricity and strength properties to the heterogeneous braid than PET.

55. My opinion regarding the "function" of the first fiber-forming material is supported by the '446 Patent. The '446 Patent explains that the first fiber forming material is "dissimilar" to the second fiber and the braid of dissimilar yarns provides "outstanding properties attributable to the specific properties of the dissimilar fiber-forming materials which make up the braided yarns" (Tab D at 2:50-52; 3:43-48). Further, the '446 Patent explains that it is possible to "tailor the physical" properties by "varying the type and proportion of each of the dissimilar fiber forming materials used" (Tab D at 2:58-61). Further, the patent notes that the different fiber components make different relative contributions to one or more properties of the heterogeneous braid (Tab D at 8:19-21).

56. It is my opinion that the UHMWPE in Arthrex's FiberWire™ and TigerWire™ products has the function as the claimed first fiber-forming material based on an examination of FiberWire™ and TigerWire™ and its manufacturing. In my opinion, the UHMWPE contributes a property or properties that is/are different from the property or properties contributed by the PET. For example, Mr. Hallet testified that, in the development of FiberWire™, he had constructed a 100% homogeneous UHMWPE braid, but Arthrex had requested a less stiff braid. Mr. Hallet then made a heterogeneous braid of UHMWPE and PET to get the strength of UHWMPE and the flexibility of PET (Hallet 1/12/06 Dep. at p. 306:17-307:14; DMI Ex. 324; *see also* Hallet 1/12/06 Dep. at p. 307:15-308:14; DMI Ex. 325).

57. In my opinion, the "way" of the first fiber-forming material is the same as the "way" of UHMWPE in Arthrex's FiberWire™ and TigerWire™ suture products:

Claims 1, 2, 8, 9, and 12 Limitation	**"Way" of Limitation Under the Doctrine of Equivalents**	**Way UHMWPE performs its Function in FiberWire™ and TigerWire™**
a) each yarn from the first set is composed of a plurality of filaments of a first fiber-forming material selected from the group consisting of PTFE, FEP, PFA, PVDF, PETFE, PP and PE; and	The "way" is at least one yarn from the first set of yarns is in direct intertwining contact with at least one yarn from the second set.	At least one UHMWPE yarn is braided with at least one PET yarn in direct intertwining contact (Dreyfuss 9/16/05 Dep. at p. 99-107).

58. My opinion regarding the "way" of the "first fiber-forming" element is supported by the '446 Patent. The '446 Patent explains that the way that the first-fiber forming material performs its function is by braiding it with a second dissimilar yarn in direct intertwining contact For example, the '446 Patent states in the "Summary of the Invention" section that the "the invention is a heterogeneous braid comprising a first and second set of discrete yarns in a sterilized, braided construction" and that the at least one yarn from the first set is in "direct

intertwining contact" with a yarn from the second set (Tab D at 2:40-44; *see also* 3:21-28; 3:40-45). The '446 Patent further explains that the heterogeneous braid properties are due to the "mechanical interlocking or weaving of the individual yarns" (Tab D at 2:56-58; 3:43-48). Also, during the prosecution history, the applicants explained that the beneficial properties are due to the braiding of direct "<u>intertwining</u>" contact of dissimilar yarns (December 2, 1992 Office Action at 2, emphasis original).

59. Further, the '446 Patent describes certain preferred embodiments in which the first fiber-forming materials act as lubricating yarns and the second fiber-forming materials provide strength (Tab D at 4:9-59). The '446 Patent also describes other specific preferred embodiments that have PTFE braided in direct intertwining contact with PET to obtain the benefits of each yarn (Tab D at 7:1-8:61). These are all preferred embodiments where the at least one first-fiber forming material is braided in direct intertwining contact with at least one different, second fiber-forming material so that each yarn contributes to the heterogeneous braid. Because these are preferred embodiments, they are an example of the broader disclosed concept of braiding the first and second fiber forming materials so that they can individually contribute to the overall properties of the heterogeneous braid. Notably, the invention is described more broadly than just these "preferred embodiments," and, therefore, it is my opinion that neither the function, way, or result is limited to the specific properties of the first-forming material in any of the preferred embodiments.

60. It is my opinion that the UHMWPE in Arthrex's FiberWire™ and TigerWire™ suture products have the same "way" as the claimed first-fiber forming materials. My opinion is based on a visual inspection and observation of FiberWire™ and its manufacturing processes. In my opinion, at least one UHMWPE yarn in Arthrex's FiberWire™ and TigerWire™ products is

braided in direct intertwining contact with at least one PET yarn. My opinion is supported by Arthrex's and Pearsalls' testimony and documents. For example, Mr. Dreyfuss testified that the adjacent yarns in the FiberWire™ and TigerWire™ sheath are in direct intertwining contact with each other (Dreyfuss 9/16/05 Dep. at p. 99-107).

61. In my opinion, the "result" of the first forming material is the same as the result of UHMWPE in Arthrex's FiberWire™ and TigerWire™ suture products:

Claims 1, 2, 8, 9, and 12 Limitation	**"Result" of Limitation Under the Doctrine of Equivalents**	**Result of UHMWPE in FiberWire™**
a) each yarn from the first set is composed of a plurality of filaments of a first fiber-forming material selected from the group consisting of PTFE, FEP, PFA, PVDF, PETFE, PP and PE; and	The result of the first set of yarns is to contribute to the heterogeneous suture braid a property different from the yarn in the second set, so that when they are braided the yarns contribute to the properties of the overall heterogeneous braid.	The result of the PE yarns is to provide a different property than the PET, so that when they are braided the PE yarns contribute properties to the overall heterogeneous braid.

62. My opinion regarding the "result" of the first-forming material is supported by the '446 Patent. For example, the '446 Patent explains that the "heterogeneous braids may exhibit a combination of outstanding properties attributable to the specific properties of the dissimilar fiber-forming materials" (Tab D at 2:49-52). Further, the '446 Patent states that the "types of yarns used to prepare the heterogeneous braid and the yarn geometry can be varied to prepare heterogeneous braids within the scope of the claimed invention which exhibit a combination of outstanding physical or biological properties." (Tab D at 1:51-56).

63. My opinion is that FiberWire™ and TigerWire™ suture products have the same claimed result. UHMWPE has and contributes properties that are different from those provided by PET. For example, Arthrex has admitted that the UHMWPE is added to FiberWire™ to increase strength. (Arthrex supplemental response to Interrogatory No. 3) In FiberWire™, when

the UHMWPE is braided with PET, it is my opinion that the UHMWPE contributes to the strength of the overall heterogeneous braid. Further, UHMWPE is known to have relatively high lubricity and has different lubricity than PET.

64. My opinion is further supported by the testimony and documents from Arthrex and Pearsalls witnesses:

> Q What did you understand Mr. Grafton to mean when he said:
> "Can you build a 25% Dyneema/75% polyester blend in Size 2 that is very flexible".
> What did you understand that to mean?
> A Yes, that he wanted a braid which was more -- not so stiff.
> Q As the 100% ultra high molecular weight polyethylene?
> A Yes. (Hallet 1/12/06 Dep. at p. 306:20-307:4, DMI Ex. 324)

> Q. Mr. Grafton wanted Pearsalls to braid polyester with the ultra high molecular weight polyethylene so that the polyester could provide flexibility?
> A Yes. (Hallet Dep. at p. 307:10-14, DMI Ex. 324)

65. It is my expert opinion that both of the above documents and testimony demonstrate that Arthrex is "tailor[ing] the physical" properties of the braid by "varying the type and proportion of each of the dissimilar fiber forming materials used" as taught by the '446 Patent (Tab D at 2:58-61).

66. In summary, if it is determined that PE is not PE (does not include UHMWPE), it is my opinion that the ultra high molecular weight polyethylene in Arthrex's FiberWire™ and TigerWire™ suture products is equivalent to the claimed PE because it performs the same function, in the same way to achieve the same result. Any differences are insubstantial in the context of the invention.

VI. Opinions Regarding Contributory Infringement

67. I understand that contributory infringement is defined in 35 U.S.C. §271(c), which provides:

> Whoever offers to sell or sells within the United States or imports into the United States a component of a Patented machine, manufacture, combination or composition, or a material or apparatus for use in practicing a Patented process, constituting a material part of the invention, knowing the same to be especially made or especially adapted for use in an infringement of such Patent, and not a staple article or commodity of commerce suitable for substantial noninfringing use, shall be liable as a contributory infringer.

68. I understand that an act of actual direct infringement is necessary for a finding of contributory infringement. If there is direct infringement, then there is contributory infringement if the remaining requirements of the statute are satisfied.

69. I have been asked to provide my opinion as to whether Pearsalls has sold within the United States or imported into the United States a component of a patented suture that constitutes a material part of the invention in claims 1, 2, 8, 9 and 12 of the ‘446 patent. It is my opinion that Pearsalls has sold within the United States or imported into the United States a component of a patented suture constituting a material part of the invention in claims 1, 2, 8, 9 and 12 of the ‘446 patent.

70. It is my understanding that Pearsalls makes all of the braids used in Arthrex’s FiberWire™ and TigerWire™ suture products. (Arthrex’s Response to Mitek Interrogatory #2). Pearsalls imports into the United States unsterile, FiberWire™ and TigerWire™ suture that has not been cut to length or tipped. I personally observed the Pearsalls braided product at the final inspection stage before shipment. Pearsalls also sells within the United States this unsterile, FiberWire™ and TigerWire™ suture to R.K. Manufacturing (Ponton Dep. at p. 17:23-18:12).

71. It is my opinion that the unsterile FiberWire™ and TigerWire™ that Pearsalls imports and sells is a component of the invention of claims 1, 2, 8, 9 and 12 of the ‘446 Patent. The imported and sold FiberWire™ and TigerWire™ has the same construction as that sold by Arthrex except for some processing operations such as tipping, attachment to anchors or needles, and sterilization. (Ponton Dep. at p. 18:18-21). Thus, the imported and sold FiberWire™ and TigerWire™ has all of the limitations of claims 1, 2, 8, 9, and 12 except that it is not sterilized. It has a braid construction of polyethylene and PET in direct intertwining contact. Further, each has a core except for size 4-0 FiberWire™. Thus, the FiberWire™ and TigerWire™ that is sold and imported by Pearsalls is a component of the claims of 1, 2, 8, 9, and 12 and a material part of the invention of claims 1, 2, 8, 9, and 12.

72. I have been asked to provide my opinion as to whether the FiberWire™ and TigerWire™ imported and sold by Pearsalls is especially adapted for use for infringement of claims 1, 2, 8, 9, and 12 of the ‘446 Patent, and not a staple article or commodity of commerce suitable for substantial non-infringing use. It is my opinion that the FiberWire™ and TigerWire™ imported and sold by Pearsalls is especially adapted for use in an infringement of the ‘446 Patent, and not a staple article or commodity of commerce suitable for substantial noninfringing use. The ‘446 Patent claims a suture. It is my understanding that RK Manufacturing does nothing to alter the FiberWire™ and TigerWire™ surgical braid. (Ponton Dep. at p. 18:18-21). The FiberWire™ and TigerWire™ imported and sold by Pearsalls has no known use other than as a suture, which is claimed in the ‘446 Patent. Thus, the FiberWire™ and TigerWire™ that is imported and sold by Arthrex is not a staple article of commerce and has no known substantial noninfringing use other than that that has been identified. (Pearsalls’ Answers to Mitek’s First Set of Interrogatories).

VII. Other Issues

73. It is my opinion that some of the benefits of FiberWire™ and TigerWire™ that are marketed by Arthrex are due to the patented invention, a heterogeneous braid of dissimilar non-bioabsorbable yarns of the type claimed, where at least one yarn from the first set is in direct intertwining contact with a yarn from the second set, and the dissimilar yarns have at least some different properties that contribute to the overall properties of the heterogeneous non-bioabsorbable braid.

74. For example, Arthrex markets that FiberWire™ has superior strength, increased stiffness, and has been "enthusiastically endorse[d]" for "its feel." (DMI Ex. 7 at 2). FiberWire™'s and TigerWire™'s ultra high molecular weight polyethylene braided yarns contribute to FiberWire™ and TigerWire™'s strength and stiffness (Hallet 1/12/06 Dep. at p. 306:17-307:14; DMI Ex. 324; *see also* Hallet 1/12/06 Dep. at p. 307:15-308:14; DMI Ex. 267). Further, FiberWire™'s and TigerWire™'s PET contributes to the flexibility of the braid (DMI Ex. 324). Notably, the patented invention of claims 1, 2, 8, 9, and 12 includes a heterogeneous braid of PE and PET. Further, the '446 patent explains that a heterogeneous braid of dissimilar materials in direct intertwining contact can contribute to the overall properties of the heterogeneous braid (Tab D at 2:50-52; 3:43-48). Further, the '446 patent teaches that the braided yarns can be tailored in type and amounts to obtain the properties of each (Tab D at 2:58-61). FiberWire™ and TigerWire™ do just that by braiding polyethylene and PET. Thus, it is my opinion that benefits touted by Arthrex are due to the patented invention.

75. Arthrex's and Pearsalls' development of FiberWire™ and TigerWire™ confirms my opinion. For example, Mr. Hallet testified that in the development of FiberWire™ he had constructed a 100% homogeneous UHMWPE braid, but Arthrex had requested a less stiff braid. Mr. Hallet then made a heterogeneous braid of UHMWPE and PET to get the strength of

UHWMPE and the flexibility of PET (Hallet 1/12/06 Dep. at p. 306:17-307:14; DMI Ex. 324; *see also* Hallet 1/12/06 Dep. at p. 307:15-308:14; DMI Ex. 325).

76. It is my opinion that the braiding of dissimilar materials in direct intertwining contact in FiberWire™ contributes to the properties advertised by Arthrex in its marketing literature. For example, Arthrex has marketed that "that FiberWire™ is a "Braided Polyblend Suture" that it is "revolutionizing Orthopaedic Surgery" (DMI Ex. 7 at 1). I also note that Arthrex's claims that its FiberWire™ heterogeneous braid has superior properties is supported by "multiple scientific publications" (DMI Ex. 7 at 2). Thus, Arthrex is highlighting the braiding of dissimilar materials as claimed in claims 1, 2, 8, 9, and 12 of the '446 Patent.

77. Further, Arthrex has made many assertions that FiberWire™'s heterogeneous braid is superior to Ethibond's homogeneous braid. For example, Arthrex claims that the FiberWire™ is "twice as strong" as "polyester suture" (DMI Ex. 9 at 2; DMI Ex. 10 at 2; *see also* DMI Ex. 11; DMI Ex. 24 at ARM001473). Arthrex also asserts that "FiberWire™ has twice the strength of the similar *sized generic suture* with superior feel, tie ability, and lower knot profile" (DMI Ex. 13; emphasis added). Arthrex claims that its studies show that FiberWire™ has better knot strength than "Ethibond Excel braided polyester suture" (ARM002177-8; ARM002181-83; ARM002188-2191). It is my opinion that the braiding of polyethylene and PET in direct intertwining contact contributes to FiberWire™'s properties of strength and flexibility that Arthrex markets with respect to Ethibond.

78. At trial, I may use demonstrative exhibits. For example, I may use demonstrative exhibits to explain the design and construction of Arthrex's FiberWire™ and TigerWire™ suture products, to explain infringement, and to explain the other opinions that I have set forth in my report.

Dated: March 3, 2006

David Brookstein, Sc.D.
Fellow-American Society of Mechanical Engineers

CERTIFICATE OF SERVICE

I certify that the foregoing Expert Report of Dr. David Brookstein was served by e-mail without exhibits and Federal Express overnight mail (Saturday delivery) with exhibits on March 3, 2006 on the following:

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Dated: March 3, 2006

Erich M. Falke

EXHIBIT 5

UNITED STATES DISTRICT COURT

DISTRICT OF MASSACHUSETTS

C.A. NO. 04-12457 PBS

____x

DePUY-MITEK, INC.,

A Massachusetts Corporation,

Plaintiff,

vs.

ARTHREX, INC.,

A Delaware Corporation,

Defendants.

____x

CONFIDENTIAL - OUTSIDE COUNSELS' EYES ONLY

DAY 1 OF 2

DEPOSITION OF DR. DAVID S. BROOKSTEIN

Philadelphia, Pennsylvania

July 26, 2006

Reported by:

PAMELA HARRISON, RMR, CRR, CSR

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that would be permeation. 01:15:30p
Q. And what's the difference between permeation and impregnation? 01:15:32p 01:15:34p
A. It's basically the same. 01:15:37p
Q. And would it make a difference to -- your opinion is that the coating does not permeate -- which word would you like to use, permeate or impregnate? 01:15:39p 01:15:43p 01:15:45p 01:15:49p
A. It doesn't matter. 01:15:51p
Q. Let's just use permeate. 01:15:52p
Is it your opinion that the coating does not permeate the braid? 01:15:54p 01:15:55p
A. That is correct. 01:15:57p
Q. And is that -- would your opinions change if the coating did permeate the braids? 01:15:58p 01:16:04p
MR. BONELLA: Object to the form. Hypothetical. 01:16:08p 01:16:09p
THE WITNESS: To what -- I would have to know to what extent it permeated. I'd have to know -- there's a second piece of information, you know, which I determine that was the percent of resin that the final suture was composed of. 01:16:13p 01:16:13p 01:16:16p 01:16:18p 01:16:20p 01:16:23p
BY MR. SABER: 01:16:25p
Q. Well, could you explain to me -- and I 01:16:25p

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understand you did provide some information on that. Could you explain to me why -- strike that. 01:16:27p 01:16:30p 01:16:37p
If I understand your -- is it your testimony that if it permeated -- if the coating permeated the braid, it might affect your opinions even though there are other factors? 01:16:37p 01:16:39p 01:16:42p 01:16:45p
A. If it permeated to a large extent, it might. 01:16:48p 01:16:51p
Q. And why would that be? 01:16:51p
A. Because it then could start to affect the way the braid -- the way the two yarns interact with each other. 01:16:52p 01:16:54p 01:16:57p
Q. Under your view of basic and novel characteristics -- 01:16:59p 01:17:05p
A. Yes. 01:17:05p
Q. -- and is this -- your opinion that it might affect your opinion, is that based on your understanding of what the basic and novel characteristics would be? 01:17:06p 01:17:10p 01:17:13p 01:17:15p
A. It's based on my understanding of the basic and novel characteristics in my experiencing coating yarns and fabrics as textile engineered structures, yes. 01:17:16p 01:17:18p 01:17:20p 01:17:28p
Q. The -- but your understanding or at 01:17:29p

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least your assumption of basic and novel characteristics is that it has two yarns in direct intertwining contact where each contributes a different property to the yarn, correct? 01:17:32p 01:17:36p 01:17:37p 01:17:40p 01:17:42p
A. Well, let me -- 01:17:45p
Q. I don't mean to -- 01:17:45p
MR. BONELLA: It mischaracterizes the former testimony. 01:17:45p 01:17:48p
THE WITNESS: I want to read precisely what I'm saying about the basic and novel characteristics. 01:17:50p 01:17:51p 01:17:53p
BY MR. SABER: 01:17:54p
Q. Right. 01:17:54p
A. I have been asked to assume that the basic and novel characteristics are a heterogeneous braid of dissimilar non-bioabsorbable yarns of the type claimed, where at least one yarn from the first set is in direct intertwining contact with a yarn from the second set, and the dissimilar yarns have at least some different properties that contribute to the overall properties of the braid. 01:17:54p 01:17:56p 01:17:58p 01:18:01p 01:18:06p 01:18:08p 01:18:11p 01:18:12p 01:18:15p
Q. Now, could the permeation of the coating affect that the yarns are dissimilar? 01:18:17p 01:18:18p

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A. No. 01:18:24p
Q. Could it affect that the yarns are non-bioabsorbable? 01:18:25p 01:18:28p
A. No. 01:18:32p
Q. Could it affect that the yarns are in -- that at least one yarn from the first set is in direct intertwining contact with the yarn from the second set? 01:18:33p 01:18:37p 01:18:39p 01:18:41p
A. I don't think so. 01:18:42p
Q. Could it affect that the dissimilar yarns have at least different properties that contribute to the overall properties of the braid? 01:18:43p 01:18:45p 01:18:50p 01:18:52p
A. Can you repeat that, please? 01:18:57p
MR. SABER: Could you read it back, please. 01:18:59p 01:18:59p
(The court reporter read the record as follows: 01:19:00p 01:19:00p
"QUESTION: Could it affect that the dissimilar yarns have at least different properties that contribute to the overall properties of the braid?") 01:19:00p 01:19:00p 01:19:00p 01:19:00p
MR. BONELLA: What's the question; what could it affect? 01:19:10p 01:19:11p
MR. SABER: Coating permeating 01:19:12p

the braid. 01:19:14p
MR. BONELLA: Okay. Let's get a 01:19:15p
complete question. 01:19:16p
BY MR. SABER: 01:19:17p
Q. Let me rephrase it just to try and 01:19:17p
deal with Mr. Bonella's objection. 01:19:19p
Could coating permeating the 01:19:21p
braid affect the dissimilar yarns having at least 01:19:23p
some different properties that contribute to the 01:19:29p
overall properties of the braid? 01:19:31p
A. If you had full permeation, the braid 01:19:34p
-- the yarns would still contribute to the 01:19:38p
properties of the braid but then there could be a 01:19:41p
problem associated with the fibers slipping by 01:19:43p
each other. 01:19:46p
Q. Well, under your theory of basic and 01:19:47p
novel and of materially affect basic and novel, 01:19:49p
why would that affect basic and novel 01:19:56p
characteristics? 01:19:58p
A. I guess it would not. 01:19:58p
Q. Okay. What experience -- have you 01:20:00p
ever done this kind of scanning electron 01:20:14p
micrograph testing before? 01:20:17p
A. 30 years. 01:20:18p
Q. You've been doing it for 30 years? 01:20:19p

A. Yes. 01:20:20p
Q. Have you ever done it on sutures 01:20:21p
before? 01:20:22p
A. Not that I can recall. 01:20:23p
Q. Have you ever done it to try to 01:20:25p
identify whether -- where and whether there is 01:20:28p
coating on a structure? 01:20:32p
A. Over the 30-year period, very 01:20:33p
frequently. 01:20:36p
Q. Okay. On what -- on what -- but 01:20:36p
you've never done that for a suture, correct? 01:20:39p
A. That's correct. 01:20:41p
Q. On what materials have you used this 01:20:42p
scanning technique to judge where and -- where 01:20:45p
and how much coating there is? 01:20:57p
A. I've done it on most of the yarns that 01:20:58p
are measured in the first and second set -- 01:21:01p
excuse me; most of the fibers that are in the 01:21:04p
first and second set. I've done it in my work in 01:21:06p
composite materials. I've done it in my work in 01:21:09p
flexible structures. I've done it, yes. 01:21:11p
Q. Have you done it on braided 01:21:16p
structures? 01:21:18p
A. Yes. 01:21:18p
Q. Have you done it for the purpose of 01:21:19p

trying to understand whether the coating is on 01:21:20p
the surface of the braided structure or permeates 01:21:24p
the braided structure? 01:21:27p
A. Yes, I have. 01:21:28p
Q. Okay. Which specific materials have 01:21:29p
you done that for? 01:21:31p
A. I've done it -- I did it with a 01:21:32p
project that's listed in my CV, it was a 01:21:34p
non-patented product, I made an air beam for the 01:21:37p
Army, and that was a braided structure, and we 01:21:42p
applied a coating, and I had to see to what 01:21:45p
extent the coating would -- was permeating and 01:21:48p
how that would affect the properties of the air 01:21:52p
beam. 01:21:53p
Q. What was the air beam made of? 01:21:53p
A. I don't recall. 01:21:57p
What fibers? 01:21:58p
Q. Yes, sir. 01:21:59p
A. I don't recall. 01:22:00p
Q. What's an air beam? 01:22:01p
A. An air beam is a braided structure 01:22:02p
that's used to -- like an intertube, if you 01:22:05p
will. It's 180 -- roughly 180 degrees, it's 01:22:10p
pumped up with air, and it replaces steel in the 01:22:14p
military structure. 01:22:19p

Q. In what kind of military structure? 01:22:20p
A. Hangars, tents, things like that. 01:22:21p
Q. Other than the experience with the air 01:22:26p
beam, have you done this test on other braided 01:22:35p
structures to see where the coating exists and 01:22:38p
whether it permeated the braided structure? 01:22:42p
A. Yes. I had a project many years ago 01:22:45p
making truss cords for the Army, and we were 01:22:46p
impregnating, putting resin on, and I had to 01:22:51p
determine to what extent the resin went through 01:22:55p
the structure. 01:22:57p
Q. What's a truss cord? 01:23:03p
A. It's a structural member for a bridge. 01:23:05p
Q. Do you know what the truss cord was 01:23:09p
made of? 01:23:11p
A. The fibers were carbon fibers. I 01:23:11p
don't recall the resin. 01:23:14p
Q. Excuse me? 01:23:15p
A. The fibers were carbon fibers. I 01:23:15p
don't recall what the resin was, the coating. 01:23:18p
Q. And when did you do this -- this test 01:23:23p
with the truss cord? About how long ago was 01:23:26p
this? 01:23:30p
A. 20 years ago. 01:23:32p
Q. And how about the air beam one; when 01:23:32p